INFECTED BLOOD INQUIRY

WRITTEN SUBMISSIONS

ON BEHALF OF WATKINS & GUNN CORE PARTICIPANTS

"We still have no closure, no admission of wrongdoing.
Everything has been swept under the carpet and no one listened."

Mary Grindley
1 November 2019

1. These submissions focus on the main issues with which our clients are concerned. Many of our clients have a particular interest in events in Northern Ireland and Wales. We will also pay attention to HBV, which is a terrible disease deserving of recognition. We do not intend to cover every topic. The Inquiry has an extensive team and a detailed knowledge of the evidence. As such we will not rehearse evidence, save for references to key documents and excerpts of the oral evidence where necessary to develop a point.

2. This Inquiry should have been held decades ago when events were fresher, memories sharper, and more key witnesses would have been able to give evidence. Importantly, many infected and affected who are no longer with us would have been able to bear witness to this Inquiry and the findings which it will make. No adequate explanation has been put forward by any of the Ministers or civil servants as to why this Inquiry was not held sooner. In short, the line taken by Government – that patients received the best treatment available given the medical knowledge at the time – became entrenched, notwithstanding that it was wrong, at the expense of an open-minded review of the position. This theme will be addressed further below in the context of openness, candour, and cover-up.

3. These submissions will address the following issues in order:

a. Future compensation and support;
b. Findings to be made in relation to the disparate trusts and schemes which were established;
c. Failure to achieve self-sufficiency, the failure of the Welsh Office and the Northern Ireland Office and the conflict of interest at the epicentre;
d. Failure of the regulation of blood and blood products;
e. Findings to be made in relation to blood transfusion practice and policy;
f. Openness, candour, and cover-up;
g. The omission of persons infected with HBV from the support schemes;
h. Suggested recommendations.

4. We wish to emphasise at the outset that our clients do not see this Inquiry as the end of a long journey; it is one important juncture. It is for that reason that we begin these submissions by looking forward to what should be done to attempt to alleviate the problems that the infected and affected continue to suffer.

An approach to the Compensation for the Infected and Affected

What should be done?

5. Our proposals for the scheme of compensation, structurally, on the issue of eligibility and on the calculation of quantum, are based primarily on;
   a. The evidence of the infected and affected;
   b. The Recommendations and oral evidence of Sir Robert Francis KC;
   c. The evidence the Inquiry has received concerning the means and systems of providing compensation and support in other countries, particularly the Republic of Ireland;
   d. The present systems used in the four countries for the support of the infected and affected;
   e. The existing common law systems operated in the four countries of the UK.

6. The role of compensation is of the utmost importance; it represents a clear, unambiguous acknowledgment of the acceptance of responsibility for this disaster – including HCV, HIV, HBV and vCJD – by the UK and Devolved Governments. The mealy-mouthed words previously used by them to justify the minimal amounts of money they provided can be put behind us – responsibility is accepted.

7. Further, this should be seen as an acknowledgement by them of a continuing obligation to provide appropriate, fair and reasonable, compensation and support in the future.

8. The four existing systems for the provision of financial support for those infected and affected should be amalgamated as a single new system for compensation and support. Until the new system is up and running the amounts paid to the infected and affected will be given parity, so that under the respective headings of loss, each claimant will be paid the maximum allowed under each scheme.

9. The UK Government should establish a single scheme by which each of those infected and affected, receive fair, just, and equitable compensation for the harm they have suffered and, in most cases, will continue to suffer for many years into the future. The compensation paid should be the same wherever the recipient lives. In order to meet these requirements, the system should be founded on the following principles:
    a. We adopt those principles set out in SRF's Report at para 4.75;
    b. The purpose of the scheme is to ensure that everyone who is entitled to compensation receives compensation;
    c. The scheme should be set up on an arms-length basis;
    d. The scheme must be judge-led;
    e. The scheme must be wholly independent of government, whether UK-wide or devolved;

f. There must be a dynamic, vigorous, and proactive approach to identifying those entitled to compensation. All possible methods must be used;
g. Although there may in some claims be disagreement concerning the entitlement of compensation or of the amount of compensation, the process of making a claim and resolving the amount of compensation must, so far as is possible, be dealt with in a non-adversarial way;
h. The purpose of the process is one where the infected and affected are to receive the appropriate amount of compensation, not one where pressure is applied, direct or indirect, to accept less than the claim is worth;
i. A person seeking compensation should not be required to waive their rights to pursue litigations;
j. The issues as to whom should receive compensation and the amount that should be paid, should be resolved as soon as is reasonably practicable, however, this has to be balanced against the understandable desire of the infected and affected to have careful consideration given to their own individual case;
k. The infected and the affected should have an official, unambiguous apology from the UK Government for the harm caused to the infected and affected, and an open acceptance by the UK Government that the need for compensation arises because of their responsibility for the harm the infected and affected have suffered;
l. The compensation is paid as of right, not as a matter of charity;
m. Those recruited to run the scheme must be provided with appropriate training in all aspects of their respective roles, and be familiar with the Nolan principles;
n. Contrary to the position taken by SRF, those we represent would wish to have the opportunity to be legally represented, paid for by the UK Government, so that they can receive appropriate advice and reassurance regarding the process of seeking an award of compensation, advice regarding the various types of compensation, and support and

full explanation for any decision they may have to make in respect of eligibility and quantum;

o. It would be wholly inappropriate for the infected and affected to have to rely on the guidance and support of employees of an institution which is financed by the body paying their compensation. Given their previous experience of the trusts and schemes, where they were treated with distain, contempt, and distrust, dealt with as beggars seeking charity, not as a person who had a right to compensation, and where those who were acquiescent in this regime might be treated more generously than those who tried to stand up for their rights. Waiting for a relationship of trust to develop between the infected and affected, and those seeking to administer the scheme would take too long. In order to make sure that the process of assessing the amount of compensation to be awarded proceeds as smoothly and quickly as possible, the UK Government should finance the provision of legal advice and representation of the applicant;

p. There are further advantages in having legal representation;

   i. The application for compensation will necessarily require detailed consideration of the applicants' medical records, which sometimes will extend to a number of lever arch files. This is likely to be a traumatic and upsetting process for the claimant as they are reminded of the many painful events which have occurred, and which in many cases will continue into the future. This may be less traumatic if they able to rely on legal representatives who already know the background to the scheme and the issues that may need to be explored in any individual case;

   ii. Their medical records are likely to contain private and confidential information which should be shared as little as possible;

   iii. Their present solicitors will have access to their medical records, and they will know, and so will therefore be able to start

processing their application for compensation immediately, although, of course, they will be entitled to instruct other solicitors if they so wish;

iv. We understand that in the compensation phase of the Windrush scandal, legal difficulties have been encountered, such as, who shall bring a claim for losses arising from the death of an infected person and how is the award to be divided. These types of issue are more likely to be resolved with the assistance of a trusted solicitor;

q. In so far as may be necessary, the UK Government shall fund the instruction of such independent medical experts as the person claiming compensation may reasonably require;

r. Those who receive compensation shall be entitled to an annual sum to pay a financial advisor to help them invest the compensation and to manage their financial affairs;

s. The new scheme shall be centrally controlled and funded by the UK Government;

t. The amount of money required to fund the scheme shall be provided by the UK Government on an annual basis. There will be no reserves maintained by the body administering the scheme;

u. The new scheme will be capable of being accessed locally to ensure that, as far as possible, a trusting relationship develops over time between those administering the scheme and those receiving compensation;

v. The scheme should be co-designed by a committee which should include representatives of the infected and affected, so as to ensure that appropriate weight is given to their interests and concerns;

w. There should be a representative of those infected and affected on any group, sub-committee, or panel involved in setting up the scheme.

x. The infected and affected should be invited to play an active and collaborative approach in the continuing development of the scheme.

y. Every effort should be made to ensure that the infected and affected are not cut adrift or simply drift away from the Tribunal or scheme.

The framework of the Scheme

10. There should be established a judicial body known as the Infected Blood Tribunal. The lower level should make initial decisions on eligibility and quantum. The adjudicators should be of such calibre as to engender in those making an application, confidence and trust in their independence and ability.

11. Those making decisions affecting eligibility and quantum should be experienced in the assessment of damages for personal injury claims and the assessment of relevant medical matters. They should receive training in the possible effects of the relevant diseases. They should be provided with information concerning why this disaster occurred and the devastating effect it has had, and continues to have, on individuals and families. They should be told of the way the infected and affected have had to fight for justice for many decades against intransigent, uncaring and defensive governments.

12. The rules and procedures of the tribunal should be clear, straightforward, and well publicised.

13. The tribunal shall be presided over by a circuit judge.

14. In light of the behaviour of the trusts and schemes that previously controlled the systems for support the hearings should be non-adversarial. Applications shall be allowed unless there is overwhelming evidence to the contrary.

15. In respect of every decision of the tribunal a judgment must be given.

16. All meetings should be fully minuted.

17. All hearings shall be conducted in private but be fully recorded.

18. All correspondence, documents and minutes should be retained.

19. The respondent, who will allowed to have the same documents as that provided to the adjudicator, will not be permitted to ask questions of the applicant. Many of those who have sought support in the past have been treated in a hostile, dismissive or disbelieving or manner, they should not be exposed to such behaviour again.

20. The applicant may appeal on matters of principle and quantum to a higher level where the adjudicator shall be a high court judge.

21. There will be a positive obligation on all tribunals to complete an application within a reasonable time limit.

22. There will be an annual audit assessing, amongst other things, the applications made, applications concluded, applications outstanding, amounts awarded.

23. Until an application is fully resolved compensation will be paid on the basis of the existing schemes, however, all applicants should receive the highest amount currently paid to any registrant under the existing four schemes, regardless of circumstances.

24. In applications made by or on behalf of someone who meets the criteria for an interim award as set out in the interim recommendations made by the Chairman of the IBI on 29/07/2022, then they shall receive the interim award.

How should the scheme be run?

25. When the scheme is established all those presently registered on the four existing schemes will automatically be transferred to the new scheme.

26. All new registrants shall automatically be registered with the new scheme.

27. Unless they come within the present interim award scheme, all affected who are eligible for compensation shall receive a suitable interim award.

28. All applicants shall have the right to file a statement(s) setting out their history, why they are entitled to compensation, the extent to which they have or will suffer harm, and all past and future financial loss (together with a schedule/list of sums sought.) In addition, they will be entitled to file such further lay evidence as they think fit. An IBI statement would be sufficient as long as it contains all or part of the relevant information required.

29. They can file reports from such experts as they think fit.

30. The respondent can file a brief reply.

31. It will be a matter entirely for the applicant as to whether they give oral evidence, and no adverse inference could be draw from their decision not to.

32. It will be a matter entirely for the applicant as to whether they call oral evidence from other lay witnesses or from their expert witnesses.

33. We adopt SRF's Recommendation 4.

Eligibility

34. Those infected and affected with HBV should be awarded compensation on the same basis as those who are infected or affected by HCV and/or HIV without the necessity to establish that it is a serious case of HBV. Subject to this amendment we adopt SRF's Recommendation 2.

35. Subject to amending sub-para a) by allowing claims for HBV as set out in paragraph D. 1 above, and deleting sub-para c), we adopt SRF's Recommendation 3. In light of the evidence received by the Inquest, including date of knowledge, self-sufficiency and the caution that should have been exercised regarding the use of blood products, given its known potential for transferring viruses, the application of dates is unnecessary.

36. We recommend that those infected but self-cleared (negative PCR), shall be entitled to register with the new scheme. Appropriate bands should be created to allow claims to be made for any harm suffered, in particular, any shock or distress experienced on being informed that they may have been exposed to contaminated blood.

37. Save that the references to age at sub-paras b), c) and d) be deleted, we adopt SRF's Recommendation 5. We contend that it would be unjust and unnecessary to include age related restrictions.

38. We endorse the proposal made by SRF at page 132 of his report, that,

> *'the approach of the scheme to the assessment of eligibility, starting with the demands made on applicants for information, should be to offer all the best chance possible of establishing an entitlement, rather than to be searching energetically for reasons to exclude them.'*

39. Where there is an absence of medical records and the applicant asserts that they did receive blood products or a blood transfusion, and/or a medical expert, states that the relevant medical procedure may have involved the use of blood or blood transfusion, there should be a presumption in favour of the applicant. The burden should be on the respondent to rebut that presumption.

Assessment of Quantum of Damages

40. There are many different methods by which compensation could be calculated, but ultimately there are two main methods, namely, (1) a system based on the system of common law calculations of damage, SRF calls this a 'bespoke' method, or (2) a system based on set tariffs or bands of damages in respect of most types of loss.

41. SRF's Report analyses the pros and cons of each method of compensation and has considered various types of compensation schemes in the UK and abroad. We do not to intend to carry out a similar exercise.

42. SRF's Report adopts a more nuanced approach which is primarily tariff or band based but coupled with significant elements of a common law approach, especially in respect of the calculation of future loss of earnings and future care. In addition, even in those areas which are banded there are instances where a more flexible common law approach has been used.

43. Some of our clients are attracted by the idea of a common law approach, individually assessed compensation, a bespoke method of calculation. It appears that there is a belief that because it is a bespoke approach it is more likely to be accurate and therefore must be a more generous approach than that provided by a banded approach. Those experienced in the common law approach to compensation may think that these beliefs may be misconceived. To a greater or lesser extent, the amount awarded on a common law approach will be based on a considerable amount of guesswork which in the long term probably renders it no more accurate or generous than a banded approach.

44. The main problem with a common law approach, however, is the inevitable delay that occurs in the preparation of such a case, which is likely to differ considerably from every other case in nearly every respect. Applying some knowledge of personal injury claims and the experience of ROI, it seems to us to be inevitable that even a partial resolution of these claims for compensation

will take some considerable time. That would be intolerable to the vast majority of the clients that we represent.

45. At recent conferences many of our clients agreed that they wished the assessment of compensation to be carried out 'as fast and as quickly as possible'. They much preferred a banded approach. Having been deprived of proper, appropriate and meaningful compensation for many decades, it would be unacceptable to introduce further delay.

46. Nonetheless, we contend that if an applicant wishes to have their claim for compensation be assessed on a common law basis, then they should be permitted to do so. It may be the case that there could be alterations made to the common law approach to compensation to accommodate a more graduated approach to the assessment of compensation.

47. The following is primarily directed to the assessment of compensation as that advanced in SRF's Report, the banded approach.

48. Save that both panels should include an infected and affected person, we adopt Recommendation 6.

49. We adopt Recommendation 7.

50. We adopt Recommendation 8.

51. Save for para e), we adopt Recommendation 9. The amount awarded for bereavement under a FAA claim is often thought to be derisory, and often excludes those who most need help. Here, such an award would offer very little to those who have suffered such grievous loss and would be grossly insulting. The outstanding feature of these claims for compensation is the way in which the diseases destroyed whole families. The effects of the diseases ran throughout the families. In particular, the infected and affected families often

knew one another resulting in whole communities suffering. Apart from the infected themselves, the main victims were often their parents, their children, and their siblings (using those terms in the way defined by SRF). We believe that a suitable sum should be awarded to mark the appalling loss suffered by parents, children, and siblings. We recommend that each parent alive at the time of their child's death (regardless of the child's age), should be entitled to receive a fair and equitable amount. We recommend that each child should receive a similar amount in respect of the death of a parent, no matter what age the child was at the date of death. We recommend that each sibling should receive a similar amount, irrespective of the age of the deceased or sibling at the time of death. These awards should be paid in addition to any other sum to be paid under any other head of loss.

52. We adopt Recommendations 10, 11, 12, 13 and 15.

53. Many of our clients are concerned that when they are transferred to the new scheme, they will lose the monthly/annual payments they presently receive. We recommend that, in order to avoid confusion, it should be drawn to their attention that for those who seek a banded award, it is possible to structure the award so that, in respect of some elements of the award a lump sum can be paid, whilst at the same time their monthly/annual payments can continue.

54. Insurers must provide insurance to those infected/affected and any difference is to be underwritten by the government.

55. We recommend that in its report the Inquiry emphasises the need for appropriate compensation to be awarded in the following circumstances:

    a. Where couples were warned that they should not have a child because of the risk that one or the other might be infected with one of the relevant diseases as a result whereof they lost the opportunity of having children;
    b. Where couples were warned not to continue with a pregnancy because of the risk that one or the other might be infected with one of the relevant

diseases and as a result it was terminated, whereby they lost the opportunity of having children;

c. Where couples were warned after their child was born of the risk that one or the other might have been infected with one of the relevant diseases;

d. Women carriers of haemophilia who in the late 1970s and early 1980s sought advice from clinicians as to the risk of having a child. They were not warned of the risk of their child developing hepatitis and/or HIV. When, subsequently, it transpired that there had been a significant risk, then, even though the child was not infected, both parents and child could suffer significant shock, anxiety and upset.

56. To the extent that we have not argued otherwise, we adopt Recommendations 16 to 19.

vCJD

57. There is a scheme available to provide compensation for those infected with this terrible disease, however there is an important category of people for whom there is no compensation, namely, those who received a letter warning them that they had been, or might have been, exposed to vCJD, as a result of which they were at risk of developing that disease. Although they have not developed symptoms of this disease, the receipt of this warning letter caused severe distress, anxiety, and mental strain. In addition, because of their medical status they were, and still are, often turned down for appropriate medical treatment, in particular dental treatment.

58. Further, many in this cohort have suffered financially, because of the obligation to disclose their potential exposure to the virus through contaminated blood. As a result, they have faced considerable difficulty in obtaining and paying the increased costs of insurance and mortgages.

59. We recommend that in those case where people have been, or might have been exposed to blood contaminated with vCJD, then:

a. They should be entitled to register as an affected person;
b. They will not be entitled to an interim payment;
c. In so far as they can prove that as a result of receiving such a warning letter, they developed a psychological or psychiatric injury, then they be entitled to claim compensation set at such level as is appropriate;
d. In so far as they can prove that because of their medical status they were refused treatment, then they shall be entitled to compensation;
e. In so far as they can prove that they suffered financial loss as a result of receiving such a warning letter, including, but not limited to, the increased cost of insurance, then they be entitled to seek compensation in respect of that loss.

Devolution

60. When it came to settling the HIV litigation and establishing the MFT, the UK Government did not consider that it needed to consult with the "*territorial departments*" and the money came from HM Treasury reserves, with no consequential funding to the Four Nations – see the evidence of Sir John Major.

61. To some extent, that clear thinking was confused when the UK Government established the Skipton Fund, because a contribution was sought from the Devolved Administrations which had been established under the 1998 devolution legislation.

62. There is no rational or logical distinction to be drawn between the schemes established for those infected with HIV and those infected with HCV. The only substantial difference is that one was established before 1999 and the other afterwards. If that is the reason for the difference in the funding arrangements for the two, then the justification can only relate to the budget and the

mechanism by which funds were allocated to the Devolved Administrations. Thus the difference was one of practicality rather than principle.

63. That had the unfortunate consequence that, when EIBSS was established, Wales and Northern Ireland were cut adrift and left to establish their own support schemes, albeit that the UK Government continued to make a budget transfer to fund the payments made to those infected with HIV. That had the unfortunate consequence that disparities emerged between the schemes in the Four Nations, exacerbated by the uplift to payments made by EIBSS announced during the lifetime of this Inquiry. It is very difficult for the infected and affected to understand why support payments, previously administered through trusts established on a UK basis, differed depending upon which country they lived in.

64. The idea that the support schemes were devolved matters seems to have its origins in the dispute that emerged between England and Scotland [**DHSC0042275_129**] which was eventually determined by a joint advice by the UK and Scottish Law Officers [**DHSC0042275_012**]. They concluded that the payments proposed by Scotland did not relate to a reserved matter and was therefore devolved. However, there have been a number of Supreme Court judgments on devolution references since that advice which mean that the advice was wrong:

a. *Martin v Most* [2010] UKSC 10, (2010) SC (UKSC) 40 was a case where an increase in the summary sentencing powers of Scottish criminal courts to 12 months impliedly amended the Road Traffic Offenders Act 1988 which stated that the maximum summary sentence for offences under the Act was 6 months. The Act was a reserved matter. The Court held by a majority at §§ 31 and 59 - 60 that as the purpose of the new legislation was to re-allocate the caseload and reduce pressure on the higher courts, it was "*directed*" as Scots law and did not relate to a reserved matter. Most of what was enacted by the Westminster

Parliament (that it was an offence and the maximum penalty was 12 months) was left untouched;

b. *Re Agriculture Sector (Wales) Bill* [2014] UKSC 43, [2014] 1 WLR 2622 was a case where the Welsh Assembly passed legislation setting minimum terms and conditions of employment in the agricultural sector. Agriculture was then a conferred power, but employment and industry were not. The Court accepted at §58 that the bill "*might in principle be characterised as relating to "employment" and "industrial relations""*. Nevertheless, it held at §§ 65 – 68 that so long as the bill related to a devolved matter (the scheme of devolution was then a conferred powers model rather than a reserved powers model) it was within competence – GoWA at that time did not require that the legislation should only be categorised as relating a devolved subject.

65. See also *Christian Institute v Lord Advocate* [2016] UKSC 51 at §§ 29 – 33.

66. The joint advice of the Law Officers stated at §16 that as the Scottish Executive proposed a compensation scheme and that differentiated it from social security. However, in the event we know that what was set up was not a compensation scheme. Thus, the purpose of the Skipton Fund and the later support schemes did relate to social security and so was a reserved matter. The Law Officers' advice could not be relied upon to justify the schemes being funded by the devolved health departments.

67. Until 1 April 2018, in Wales there was a conferred powers model of devolution, rather than a reserved model as in Scotland – thus, an executive act or legislation had to relate to a devolved matter, and they were listed in Schedule 7 of the Government of Wales Act 2006. The Wales Infected Blood Support Scheme was established by virtue of the Wales Infected Blood Support Scheme (No2) Directions 2017, which were made on 30 October 2017, before the change from the conferred powers model to the reserved powers model. WIBSS did not relate to one of the areas of devolved competence set out in Schedule 7.

68. Thus, not only was the disparity between the schemes in the Four Nations unjustifiable, they were ultra vires the Scotland Act 1998 and the Government of Wales Act 2006. The Inquiry has seen correspondence to the effect that the Welsh Assembly Government received advice that support payments were not devolved. Vaughan Gething, the Welsh Minister for Health and Social Services at the material time, certainly left the Inquiry with the impression that the Welsh Government was left in the lurch by a unilateral decision by the UK Government to establish EIBSS.

69. Jeremy Hunt stated that there should not have been a difference in payments across the UK and that the UK Government did not have the ability to impose a single scheme across the UK. He also stated that there was no consequential funding for the Welsh Government when they found an additional £125m from the DoH budget in 2015.

Infected Blood Victim Commissioner

70. Once the Inquiry has reported it is likely that there will be a flurry of activity until the new scheme is up and running. Following that it is likely that public, press and government interest in this blood scandal will diminish until it becomes a distance memory. We contend that as well as,

    a. An appropriate scheme of compensation,
    b. radical improvements in their health care,
    c. and appropriate findings concerning wrongdoing,

    they have the right to expect that the continued health and wellbeing of the infected and affected is supported, advanced, and protected by some independent person or body to be established as soon as possible. They should not be forgotten or cut adrift.

71. We do not seek to replicate the established position of victim commissioner which covers all manner of issues connected with the criminal law, rather we invite the Inquiry to give consideration to the role of the Commissioner for Survivors of Institutional Childhood Abuse (COSICA), an independent organisation established by the government to assist the 'Victims and Survivors' following the Report of the Historical Institutional Abuse Inquiry in Northern Ireland, which reported in 2017. The role of the Commissioner, presently Fiona Ryan, is to 'empower Victims and Survivors to exercise their rights'.

72. The Commissioner has various statutory powers given to her, including powers to:

a. Undertake or commission research;
b. To compile information;
c. To provide advice or information;
d. To publish anything concerning their interests;
e. To make representations or recommendations to any person concerning the interests of victims and survivors.

73. We recommend that a similar Commissioner should be set up as soon as possible to represent the interests, and to protect the wellbeing, of the infected and affected.

74. The Commissioner should be given a very wide discretion as to how they carry out their duties. Thus, the Commissioner,

- Should be allowed to campaign on behalf of the infected and affected,
- Should be allowed seek higher awards of compensation,
- And make recommendations to central or Devolved governments regarding all matters affecting the lives and wellbeing of the infected and affected.

75. The infected and affected should play a part in setting up the scheme, and thereafter their views should be sought when alterations to the scheme are contemplated.

76. The Commissioner should be fully funded by, but wholly independent from, the UK Government.

77. It is important that the Commissioner is established at the outset in order to play a constructive role in the establishing of a scheme. Any delay in establishing the role may result in a loss of momentum.

Previous Trusts and Schemes

78. This section will comment upon the purposes for which the trusts and schemes were set up; whether they 'supported' the infected and the affected; the manner in which the trusts and schemes treated them and the extent to which they operated in an open and fair manner.

79. The schemes operated along similar lines, often using the same staff, especially at a senior level. For the most part we do not intend to consider each scheme separately, rather, we will take an overview of the schemes. Given the time that has elapsed since the closure of the old schemes, the setting up of the present schemes and with the prospect that a wholly new compensation scheme will be devised, we have no recommendations to make on the issues arising under this particular heading.

80. We do, however, invite the Inquiry to make the following findings:

    a. That the purpose of creating these schemes was not to provide meaningful and appropriate support for the infected and affected, rather, they were used by the UK Government as a means of avoiding any investigation into this medical disaster, whilst at the same time

appearing to provide some support to certain categories of those infected or affected;

b. The schemes were used as a smokescreen to cover up the lack of any meaningful financial or other support;

c. That the use of arms-length bodies was a device by which the UK Government could cover up their control of the activities of the schemes. The schemes operated as if they were an extension of the DoH, whilst keeping the registrants at arms-length. They did not seek to protect the beneficiaries, rather they sought to protect the DoH;

    i. In any dispute regarding the beneficiaries and the DoH, the schemes took the side of the DoH;

    ii. The schemes were not accountable to the beneficiaries, or at least they acted as if they weren't, rather they appear to have decided that they were accountable only to the DoH;

    iii. They declined to raise issues which might have caused embarrassment to the DoH. They appear to have decided that they would not 'rock the boat';

    iv. They refused to promote or advertise the schemes, preferring any potential applicants to find them;

    v. They refused to campaign for the infected and affected, in particular for more money from the DoH or public contributions;

    vi. They refused to campaign for greater social and health support for the infected or affected;

    vii. Some employees felt that their role was to hand out hush-money to prevent complaints;

    viii. Those who controlled the schemes, the Chair, the Deputy-Chair, and trustees took their lead from the DoH and from the civil servants that sat on the boards;

    ix. They followed what they regarded as the DoH line. Thus, they built up reserves of money when told, they reduced the reserves when told and they did not object when told to transfer the remaining funds to the Terrance Higgins Trust, even though the

beneficiaries of these schemes wanted the funds to be distributed to them;

x. They did not seek to empower the infected and affected;

xi. The agonisingly slow speed at which the various schemes developed illustrates the uncaring attitude of the UK Government;

d. The schemes were run in an ad-hoc, careless, inefficient, bizarre, and illogical manner, thus:

i. They employed people who, for the most part, had no previous experience of medical matters, let alone any knowledge of HIV or hepatitis;

ii. They employed people who, for the most part, had no previous experience of exercising a discretion to decide whether or not an applicant should receive support or not;

iii. They employed such people without providing any induction into their roles. They appear to have been expected to learn what they were supposed to do as they carried out their tasks;

iv. Most had little experience of financial matters. They were expected to decide whether a beneficiary should be supported by helping the person to buy their own home on a mortgage, and if so, would it be by making a grant, by a loan, by taking a mortgage on the property or by some other means? If financed by a loan or mortgage, could it be transferred to another property;

v. The beneficiaries were expected to get two quotations for every item or piece of work which they needed to be paid for, no matter how small. The schemes could refuse the request or might require lower quotations to be obtained or allow part of the request but require the beneficiary to pay the balance. This process, which was not required under the terms of the trust, would cause maximum delay, frustration and humiliation;

vi. There was no attempt to identify and reach-out to the infected and affected, to alert them that they and their family might have

been entitled to support. The evidence the Inquiry has received in respect of widows, in particular from Stevens, is that they made no attempt to contact the widows because they thought that they would have known about the various schemes by keeping in contact with the Haemophiliac Centres after the death of their husbands. This is an absurd approach to such an important issue. Clearly, if the infected or affected were unaware of the existence or purpose of the schemes then no claim would be made;

vii. There were no fixed criteria which could be used to decide whether an application for support should be granted;

viii. There were no secretarial resources;

ix. The applicant could not support their application with a statement or photograph;

x. The applicant could not support their application with medical evidence;

xi. There was no forum on the scheme's website, or if there had been one it was shut down when people became too critical of the scheme;

xii. The applicant was not entitled to attend the meeting when their application was considered;

xiii. The applicant was not entitled to give oral evidence;

xiv. The receipt of blood had to be confirmed by an applicant's medical notes, it was not sufficient that the applicant or their doctor confirmed that blood was, or was likely to have been used;

xv. No record was kept of the consideration of the claim;

xvi. If a medical opinion was sought, then it was done on an ad-hoc, informal and unreported basis;

xvii. For the most part there was no one who could advise them on benefits;

xviii. There were no regional support workers;

xix. There was no long-term plan as to how the schemes could be developed to provide support for the infected and affected;

xx. The amount of money paid was very low, and the amounts paid were inconsistent between one registrant and another notwithstanding that they wanted the same item;

xxi. The registrants were expected to apply for support from other sources, before applying to the schemes. This wasn't a requirement in the documents setting up the various schemes. The net effect of this was that the application to the schemes was unnecessarily delayed;

xxii. The applicant was not informed as to why their application had failed;

xxiii. The applicant would not be informed what additional information was required;

e. Whether deliberately or otherwise, those in charge of the schemes did not try to develop or encourage a meaningful, constructive relationship with the infected or affected. On occasions those in charge of the schemes would act in a deliberately awkward and obstructive manner. By way of example:

i. The schemes made no attempt to contact, or in any constructive way communicate, with the registrants;

ii. The schemes refused to publish any information or guidance regarding the discretionary items that could be claimed, nor the cost of the item. They seem to have thought that the registrants could not be trusted that such was their character that they would make a claim for everything they could and for the maximum amount available. As Stevens stated, if they had published such a list the 'great unwashed' would use it as a 'shopping list';

iii. This approach is somewhat ironic, given the fact that the only evidence of dishonesty is that of Foster, an employee of the schemes, who carried out a wholly unsophisticated fraud by paying cheques to the value of £400,000 to himself. Despite the absence of any evidence, or indeed allegation, of dishonesty on

the part of the infected or affected, it appears to have been them who were made subject to more stringent conditions;

iv. The registrants were not invited to take part in any important meetings with the trustees or representatives of the DoH;

v. There was no forum on the website;

vi. There was no newsletter;

vii. There was no partnership group;

viii. Their address was a secret because they didn't want unwanted callers;

ix. On occasions they would act in a hostile manner to the beneficiary;

x. The Chairs did not like infected or affected persons to argue with them;

xi. Those they did not like would be made to jump through the hoops;

xii. Stevens, Harvey, Evans, and Barlow were accused of bullying or intimidating behaviour towards the beneficiaries and the employees of the schemes;

xiii. They spoke or wrote about people who were suffering from the most appalling diseases in a condescending, grossly insulting and demeaning manner;

xiv. It is noticeable that employees comment on the fact that a number of chairs, trustees, and board members, were middle-class men, well off, and from a profession background, such as finance, or from the military. Cohen suggests that they liked the feeling of power. A number of employees comment on their lack of empathy and sympathy. They came from a different class. The general theme is that they were unable or unwilling to appreciate the great difficulties the infected and affected faced in looking after themselves and their families;

xv. They spoke about the beneficiaries in grossly insulting terms – 'the great unwashed' (Clarke,) they were 'thick', 'that lot of

moaners', 'they tried my patience', this will 'piss off the Lewis' (Stevens)';

xvi. Notwithstanding that Stevens knew that Haydn Lewis, his brother Gareth, GRO-A had HIV, he seems to have taken a certain delight in mocking or goading them. The Inquiry will no doubt remember the recording of Haydn being interviewed. He had a quiet dignity and sharp intelligence which enabled him to advance his arguments in a clear, forthright manner. There is no reason why Stevens should have referred to him in the way that he did. His behaviour was disgraceful. Many of those in positions of power in the schemes exhibited a complete disregard for the infected and affected and the dire circumstances in which they found themselves.

The interplay between the failure to achieve self-sufficiency, the failure of the devolved health systems in Wales and Northern Ireland and conflicts of interest

> *"When we went to conferences, meetings and so on…directors that were most closely associated with companies would stay in the conference hotels and have five-star etc and you could see that they were…then there were gradations and you could see that as you went lower down the usage of Factor VIII in numbers or type of centre you were, then you may have to go into three-star and four-star hotels, and you could see the dinners etc. There was quite a big difference on hospitality that people got…The bigger -- the centres that were more -- were nearer working with pharmaceutical companies and so on, people who used more of the product had a lot of support for their departments. And there were individuals being employed as consultants. I know at least one who is still working as a consultant to one of the pharmaceutical companies. There were research grants. There was all sorts of available monies from pharmaceutical companies…Now, it's sad that, it's unfortunate, because I think even now things haven't changed that much, although now they would have to declare it. And some things would be unacceptable now. What -- if the gifts went above a certain level, you know, it wouldn't be acceptable at all. But at that time it was accepted practice. It was normal practice…**some of them were the same directors who were advising the Government, or on reference -- there were reference directors who were in committees that, you know, were recommending. I mean, we wanted honest advice and, you know, it sort of made us think: well, you know, is this purely unbiased or not? You know**. I think it was unbiased. I think we got very good guidelines from UKHCDO. But it wasn't pleasant visibly to see people not declaring their interest, you know. Which they would have to now. You know, they wouldn't be allowed to do it. **It would be <u>scandalous</u>**. But at that time it was -- seemed acceptable practice to be -a Reference Centre Director to be on committees that recommended the use of Factor VIII, and they would be the advisers to the Government. And these are people are paid by the National Health Service, employed by the National Health Service…I felt sad for [BPL] that they were not able to compete on equal footing, you know, with multi-national companies."* [emphasis added]
>
> Professor Liakat Parapia
> 29 October 2020[1]

The arrival of imported concentrates, the knowledge of the associated risk of NANB and the tension between Government attempts to suppress the purchase of imported concentrates and the prevailing will of clinicians

81. In March 1973, the Chief Medical Officer for England ('CMO-E') wrote to all Senior Medical Officers (copied to Haemophilia Centre Directors ('HCDs')) on

[1] Transcript pp 162 – 167.

the topic of haemophilia treatment identifying a concern in relation to the marketing in the UK of expensive concentrates produced by two foreign firms who had recently been granted licences. He identified that the UK's production of blood products was insufficient, and that planning was required to achieve more domestic production to avoid "*very significant expenditure if amounts were bought in excess of immediate needs*" [**DHSC0100005_033**]. He set up a working party to look at the issue. That working party met in June 1974 and discussed central contracts for the purchase of concentrates from the two foreign firms. They also noted that it was originally anticipated by Dr Maycock in 1973 that the Blood Transfusion Service would be able to produce enough concentrate to achieve self-sufficiency by 1975 but that would no longer be possible "*because of financial stringency*" [**DHSC0100005_135**].

82. In December 1974 Lord Owen (Minister for Health) made the decision to invest £500,000 into BPL and PFL to increase domestic production. In a minute dated 17 March 1975 [**LDOW0000018**] Lord Owen noted that the Regional Transfusion Directors ('RTDs') were seeking to persuade clinicians to accept a steadily increasing supply of domestically produced concentrate. He noted that RTDs did not always see eye-to-eye with HCDs over the treatment of haemophiliacs as HCDs wanted to implement home prophylaxis treatment programmes "*whereas the present proposals are based on upon home treatment of a bleed when it occurs*".

83. This resulted in a letter from the DHSS to Regional Health Authorities ('RHAs') on 24 December 1974 in which the DHSS stated that it "*regards it as of the* ***greatest importance****, quite apart from the question of cost, that the NHS should become self-sufficient as soon as practicable*" [emphasis added]. It stated that plasma output needed to be increased and that with the agreement of SHHD some of the plasma would be fractionated at PFC. It stated, "*it would clearly be considerably cheaper to produce these blood products within the NHS than to buy them from commercial sources*". It reiterated "*the primary aim of making the NHS self-sufficient in AHG concentrate in 2 to 3 years*" [**CBLA0000239**].

84. During 1974, Lord Owen:

a. Knew that cryoprecipitate carried a much lower risk of transmission of non-A non-B hepatitis ('NANB') (he was told this by Professor Briggs and Dr Maycock) and encouraged HCDs to use more cryoprecipitate;

b. Knew that commercial FVIII concentrates from the USA carried a much higher risk of transmitting NANB;

c. Formed the view that the importation of blood products from the USA should cease and that was more important than enabling prophylactic treatment.

85. Lord Owen stated that the CMO-E was the person who could tell HCDs not to start prophylactic home treatment programmes, but there is no evidence that this was done.

86. In Part 2 of the World in Action documentary *Blood Money*, Dr Maycock stated that the aim was to be self-sufficient by mid-1977 and that because of PFC, Scotland had never needed to import commercial concentrate. John Watt stated that whether PFC was used to fractionate plasma from England and Wales depended upon the arrangements between DHSS and the Scottish Home and Health Department ('SHHD') but if it was used, it could meet around 50% of the demand for concentrate in England and Wales. However, the policy of DHSS was not to use PFC until BPL reached maximum capacity in 1977. Lord Owen agreed that the £1m p.a. cost of importing concentrates would be better spent on achieving self-sufficiency.

87. Dr Foster confirmed in his evidence that PFC could have fractionated plasma from England and Wales and could have fractionated around a third of the plasma from England and Wales. He disputed Dr Lane's contention that the capacity of PFC was exaggerated. Dr Robert Perry told the Inquiry that there may have been some merit in a joint approach for the development, production, and supply of plasma products for the UK-wide NHS (particularly for

providing increased benefit of scale for PFC) but this did not apparently enjoy the support of DHSS or SHHD to the extent of serious consideration or study. In the event, BPL fractionated about 90% of plasma for the UK and PFC about 10% whereas it should have been in the region of 50/50.

88. At a joint meeting of the DHSS and SHHD in August 1977 it emerged that Dr Lane, who was succeeding Dr Maycock, took a different view about sending plasma to Edinburgh for fractionation and decided to focus on production at BPL [**WITN6914043**]. At §3.3 it was pointed out by SHHD that PFC "*had been planned to cater for plasma from England and, therefore, both SHHD and DHSS were answerable to Ministers for the maximum and most economic use of the facility*".

89. Thus, by the end of 1975 the position was:

a. The DHSS had adopted a policy of self-sufficiency in concentrates based on the known risk of NANB associated with imported concentrate;
b. The CMO-E had set up a working party to address the issue and the DHSS had invested £500,000 in PFC and appreciated that the health economics indicated that it was financially prudent to invest more money in achieving self-sufficiency rather than purchasing expensive imports; and
c. The DHSS and the CMO-E appreciated that the freedom of clinicians to purchase imported concentrates for home treatment programmes needed to be managed whilst fractionation capacity at BPL was increased and arrangements with PFC were put in place;
d. Notwithstanding that knowledge, no additional money was invested to achieve self-sufficiency, no arrangements were put in place to improve PFC, and no steps were taken to suppress the increasing demand by clinicians for imported concentrates.

90. In a meeting at BPL in March 1978 [**CBLA0000744**] the DHSS noted that while it may be cheaper for BPL to produce FVIII rather than purchase commercial concentrates, increasing production at BPL would not lead to a saving as the

RHA budget would remain the same. Thus, 3 years later, the DHSS had lost sight of the safety consideration.

91. In October 1979, the Scientific and Technical Committee at BPL produced a report [**CBLA0001008**] in which Mr Dutton stated that the committee had been emphasising the need for a new plant "*for some time*" and estimated that the saving to the NHS to be in the region of £5m p.a. If BPL at that time was providing less than half of the UK's need, that meant that the investment needed in equipment (c. £20m p.a.) would be covered by the estimated savings in just 4 years.

92. In January 1981 Mr Meakins, School of Pharmacy and Pharmacology, wrote in the Times about the fact that PFC was not being used by the DHSS [**CBLA0001229**]. He stated that the insufficiency of blood products in the UK was "*largely self-imposed by bureaucracy*" and that because the health departments for England, Wales, and Scotland are independent, blood is not sent north across the border; "*In my view this state of affairs is nothing less than scandalous on the current deficiency situation which is disadvantageous to both patients and the taxpayer.*"

93. Dr Dianna Walford, Senior Medical Officer within the DHSS, told the Inquiry that the DHSS knew in 1975 that BPL was not fit for purpose. Notwithstanding that, in October 1979 the DHSS decided to spend the minimum possible on BPL and explore opportunities to privatise BPL. She accepted that if BPL was facilitated to manufacture to its capability in new facilities, it would have saved money because the reduction in expenditure on imported concentrates would quickly outstrip the capital cost of redeveloping BPL. Alternatively, the DHSS were aware in September 1980 that self-sufficiency could have been achieved by reinstating the use of cryoprecipitate as the treatment of choice and using concentrate only for special treatment [**DHSC0002199_055**]. That is not a significant change from its thinking in 1975. However, no adequate explanation has been provided as to why the DHSS did not provide guidelines to clinicians

regarding the treatment of haemophiliacs by way of a CMO letter, or otherwise. Dr Rejman accepted that the CMO had wide powers to provide guidance on medical and public health matters.

94. One major reason why the CSM did not impose conditions on the use of imported concentrate is because the yellow card system was not used by clinicians for adverse reactions to NANB. Dr Walford accepted this in her evidence. Thus, adverse reactions to NANB would not have been evidenced as a trend that would have triggered a response by CSM. Sir Michael Rawlins confirmed that three adverse reports would be referred to SEAR, but he did not recall SEAR being made aware of a link between imported concentrates and NANB. He also confirmed that it was open to the CSM to write to all clinicians with specific concerns – an option that was precluded by a failure of the yellow card system. He explained how the 'black triangle scheme' operated to remind clinicians to report adverse reactions and that CSM published a regular magazine 'Current Problems' which could contain advice or warnings as the CSM thought appropriate.

95. Not only was the policy of self-sufficiency not followed up by subsequent Governments and the medical officers, but rather it was reversed by Lord Glenarthur in 1982 when DHSS decided to invest in BPL and to have PFC to focus on Scotland and Northern Ireland [**DHSC0001674**], thereby entrenching the artificial division in fractionation to the disadvantage of patients. He went further and expressed the view that PFC was a matter for the Secretary of State for Scotland.

96. Notwithstanding that the Inquiry had been told that the CMO had wide powers to issue guidance in relation to public health matters, the dichotomy in the evidence is that the medical officers (and ministers) repeatedly stated that they would never restrict clinical freedom. That line taken by the DHSS witnesses does not bear scrutiny – clinical freedom must be restricted where necessary to protect public health; after all, that is the purpose of the CMO and

DHSS as a whole. The Public Health Administration Expert Group opined that "*too much was made of clinical freedom*".

97. A significant contributory factor to the failure to achieve self-sufficiency is that it was never agreed what that actually meant. Dr Lane explained in his draft witness statement [**CBLA0000005_002**] at §84 that Dr Maycock and some of those in the DHSS thought self-sufficiency meant the amount of concentrate which was needed to treat haemophiliacs in the same way as cryoprecipitate was used. The clinicians, however, thought it meant the amount of concentrated they wanted for their patients to lead as normal a life as possible. As demonstrated below, that difference in approach meant the use of imported concentrate grew exponentially and frustrated the efforts to achieve self-sufficiency.

The devolution dimension

98. The Public Health Administration Expert Group and Lord Owen confirmed that it was open to the Secretary of State for Wales and the Secretary of State for Northern Ireland and the respective Regional Transfusion Centres ('RTCs') in those countries to enter into arrangements with PFC. They also confirmed that each country had its own Chief Medical Officer who would provide medical advice to the administrations and write guidance for clinicians – see the evidence of Dr Hilary Pickles in particular. In respect of the RTC in Wales, no steps were taken by the Welsh Office to enter into arrangements with PFC for the fractionation of Welsh blood to remove the expenditure of the Cardiff RTC on imported concentrate and the Chief Medical Officer for Wales ('CMO-W') took no steps to reduce the growing level of demand for imported concentrates – the same can also be said of the Chief Medical Officer for Northern Ireland (CMO-NI). Dr Al-Ismail explained that he didn't know that the CMO-W had anything to do with blood safety and that he relied upon the CSM doing their job properly.

99. Dr Tony Napier, the RTD for Cardiff from 1977, agreed that it was open to him to take his own action but that he tried to work with other RTDs. He stated that the issue of self-sufficiency was not a matter of great debate locally – an answer which betrayed his lack of initiative on the subject. He admitted that was aware of the possibility of sending plasma to PFC, but he didn't consider it. Had he been aware that there was a cap on the amount of Welsh plasma that BPL could fractionate, he would have considered sending plasma to PFC. He agreed with Dr Tovey that the NBTS was suffering from constraints arising from regional development, inadequate central co-ordination and financing, and a poor integration of the activities of RTCs. Cardiff RTC could not scale up production of plasma products because of a lack of space at the RTC for plasmapheresis. Ultimately, he accepted that he did not discuss self-sufficiency with the Welsh Office but that had Cardiff RTC been resourced to produce the requisite amount of plasma, Cardiff RTC could have been self-sufficient and in that event, it was likely that the worst of the HIV transmission could have been avoided.

100. Dr Morris McClelland, RTD for Belfast, consciously formulated a plan for self-sufficiency in relation to FVIII. He accepted that the purpose of the arrangements with PFC was to achieve self-sufficiency in Northern Ireland [**RHSC0000076** at p34]. The Health Board became involved on the issue of self-sufficiency in blood products. He had regular meetings with Professor Mayne because of the rising costs of concentrate; the Health Board wanted to understand how the costs may be contained and they played a co-ordinating role between supply and demand. He tried to discourage Professor Mayne from purchasing imported concentrates. An agreement in principle was reached with SNBTS in February 1981 [**CBLA0001388**] but due to delays caused by the capacity of Belfast RTC to carry out the required testing, the agreement was not implemented until April 1982 [**CBLA0001572**].

101. Dr McClelland wrote to Dr Bridges in May 1984 [**NIBS0001719**]. In that letter he stated that PFC was fractionating all the FFP sent by Northern Ireland so

that they were self-sufficient in Factor VIII. It seems that the only product that they were not self-sufficient in was albumin. The letter does note, however, that the demand at Royal Victoria Hospital had doubled in 1983 from 1982. In evidence, Dr McClelland confirmed that they were not using 100% PFC FVIII and demand was increasing rapidly.

102. Thus, in distinction to the position in Cardiff RTC, the story of Belfast RTC is that they had a RTD and a Health Board with the foresight and desire to achieve self-sufficiency in 1981, but the plan was poorly executed in two ways: (i) a lack of investment meant that Belfast RTC could not carry out the required screening which delayed the implementation of the agreement; and (ii) no adequate control was exerted over Professor Mayne's purchase of increasing amounts of commercial concentrate because, as explained by Dr McClelland, blood products were procured and supplied directly to the haemophilia centre but the cost came out of the NIBTS budget. Unfortunately, Dr McClelland did not discuss with Professor Mayne a system whereby all products were held by the RTC – he deferred to the expertise of the clinician. That failure to implement a system whereby the clinicians in the Royal Victoria Hospital were not free to purchase as much imported concentrate as they liked in circumstances where sufficient supply of SNBTS FVIII was made available was a missed opportunity in Northern Ireland to achieve self-sufficiency and lessen the impact of HIV transmission there.

103. The theme that has emerged from the evidence of the Secretaries of State for Health and Social Services ('SSHSS') and the Ministers in the UK Government is that central government's decision-making on blood and blood products was Anglo-centric and very little thought was given to the implications for Wales and Northern Ireland. There is no evidence of discussion of the implications as between the SSHSS and the Secretaries of State for Wales ('SSW') and Northern Ireland ('SSNI'). The various SSHSS and Ministers assumed that it would be discussed at official level – however, there is no evidence before the Inquiry that it was.

104. The working party on hepatitis was established by the DHSS in 1977 after consultation with the Welsh Office but did not include a representative from the Welsh Office or the Northern Ireland Office [**DHSC0002189_014**]. Thus: (i) both the Welsh Office and the Northern Ireland Office were on notice of the working group; but (ii) they did not contribute to it and thus there was a missed opportunity to focus on the position of Wales and Northern Ireland independently.

105. There was a meeting between the DHSS, SHHD the Welsh Office and the Northern Ireland Office to discuss self-sufficiency in February 1981 [**DHSC0000064**]. It was agreed that although BPL were currently supplying England, Wales and Northern Ireland, PFC could play a role in meeting the needs of the UK. It was identified that PFC had the potential to meet around 50% of the UK's requirements for blood products. At §11 it was suggested that as BPL fractionated Welsh plasma "*and would presumably continue to do so*" it may be appropriate for the Welsh Office to contribute towards the redevelopment of BPL and similarly if PFC fractionated Northern Ireland plasma it may be appropriate for the Northern Ireland Office to contribute towards the costs of running PFC. Thus, the possibility of different countries having their plasma fractionated at either BPL or PFC was expressly considered at this meeting but what does not appear to have been considered on any evidence available to the Inquiry is the possibility of Welsh plasma being fractionated by PFC at any point up until BPL was finally redeveloped in the late 1980s, by which point it was too late to mitigate the effects of HIV or HCV upon haemophiliacs in Wales.

106. Lord Kenneth Clarke told the Inquiry that he did not remember any meetings with the Welsh Office or the Northern Ireland Office whatever and simply did not know whether they would follow the DHSS's lead. David Mellor told the Inquiry that there was no time to discuss decisions with his counterparts in the Four Nations and liaison was left to permanent secretaries and civil servants

who would take on board what they said. He went as far as to say that he did not regard it as part of his role to meet with the Four Nations. In respect of a letter from the Secretary of State for Wales complaining that he was not consulted on a decision to make payments to transfused patients [HMTR0000003_022] he stated that he did not read anything from the Welsh Office. One reading of the letter from the Secretary of State for Wales to the SSHSS as late as October 1985 [**DHSC0044118**] is that "*close liaison*" had by that point still not been established between the Welsh Office and the DHSS on the issue of AIDS. Dr Perry confirmed that when the Advisory Committee on the Virological Safety of Blood was established in 1989 the Welsh Office and Northern Ireland Office were only 'observers' rather than 'participants', even though separate and distinct decisions could be made in relation to, say, screening in those countries.

107. Dr Rejman stated that he did not have regular meetings with officials from the Four Nations and that was normally left to administrators. The exchange of information was also done by the administrators. He confirmed that there was no system or process in place by which medical advice was shared across the Four Nations. Often, it occurred to the DHSS late to notify the Four Nations of developments. He confirmed that the health departments of the Four Nations were smaller[2] so that the medical officers had a much wider role than haematology so that they relied on the work done by DHSS and the policy decisions would come from the DHSS. He confirmed that the Welsh Office and Northern Ireland Office were only observers and not participants in the ACVSB. There are three problems with that evidence:

    a. The exchange of information could only be done on the administrative side, in respect of matters with which this Inquiry is concerned, if the medical officers told the administrators what information to exchange;
    b. It can be seen from the limited documents available below in respect of the Welsh Office and Northern Ireland Office that they did not take

[2] Lady Bottomley made the point that the territorial departments were often smaller than a regional health authority.

policy instruction from Whitehall but made their own policy decisions which would be unreasonable if not based on all relevant information and that was dependent on the medical officers in the UK Government sharing all relevant information with the medical officers in the Welsh Office and Northern Ireland Office. Dr Rejman accepted that the Welsh Office and the Northern Ireland Office did not have the capacity to develop policy in the way the DHSS did;

c. The safe production of blood products in the UK is something that should have been considered on a Four Nations basis, given that the Welsh Office, the Northern Ireland Office and the SHHD were responsible for blood in their respective countries.

108. Rather, it seems to be the position that it was assumed by all the Welsh Office and the Northern Ireland Office would follow suit. But that was inappropriate because they had the advantages of being smaller and thus self-sufficiency being a more realistic prospect. Indeed, Northern Ireland did not follow England's lead and decided to pursue a policy of self-sufficiency. They could have achieved this aim were it not for clinical freedom. In Wales, the issue was simply not addressed by those with the power to take decisions and the responsibility to do so. Dr Rejman described the health department within the Welsh Office as "*very passive*".

109. Lord John Patten, Parliamentary Under-Secretary in the Northern Ireland Office January 1981 – June 1983, told the Inquiry that, generally, territorial Ministers were highly protective of their countries and that Cabinet Ministers would protect their interests. The UK Government were kept away from policy decisions and a lot of bilateralism went on. However, he also explained that when he was in Northern Ireland (at a crucial time for the purposes of this Inquiry) he did not recall seeing a single submission on blood and blood products, even though he was responsible for health and social services. This evidence is consistent with Dr Rejman's evidence that the health departments did not have the capacity to develop blood policy.

110. Thus, at the material time, the Welsh Office had the power and responsibility to make decisions in relation to blood and blood products but: (i) there was no or no adequate system in place for the exchange of medical advice between the Four Nations; (ii) the capacity of the Welsh Office to take policy decisions was inadequate; (iii) in any event, they were "*very passive*"; (iv) the UK Government did not forcibly take the lead on the issue; (v) thereby allowing Wales to navigate troubled waters without a captain.

111. The Public Health Administration Expert Group made it clear that the SSHSS was not responsible for health in Wales, Northern Ireland, or Scotland. They identified a complication in that Wales and England were integrated for the purpose of legislation and high-level policy. They commented that the lack of documentation in relation to decisions being made in Wales and Northern Ireland on blood policy may be attributable to the fact that the SSW and SSNI were not dedicated to health but had a wider policy portfolio. They were unsurprised by the evidence of the Ministers in the DHSS that they had little dialogue with their counterparts in the Four Nations as this was a reflection of the Anglo-centric approach of the DHSS. They identified that **the missed opportunity** was not creating a national blood transfusion service that made the most of both BPL and PFC – the devolution problem compounded matters as there was a failure to recognise that there were different systems in place.

The exponential increase in the use of imported concentrates

112. The evidence that the Inquiry has heard establishes that, notwithstanding the efforts made to encourage clinicians to suppress the usage of imported concentrate, it continued to grow exponentially. The reasons for this growth in the decade up to 1984 were identified in the report of the Haemophilia Society's Blood Products Sub-Committee [**PRSE0002290**] as:

    a. Increased dosage levels;
    b. Increased prophylaxis;

c. Increased usage for home treatment;
d. Increased treatment of inhibitor patients;
e. Increased surgery;
f. Increased life span.

113. Professor Ludlam, who worked under Professor Bloom in Cardiff between 1975 – 1979, confirmed that there were patients on home treatment around 1976 / 77 and there was short-term prophylaxis – treatment with concentrate every other day for three weeks. Indeed, this is something that he implemented in Edinburgh, to the extent that by 1982 his home treatment programme was using 80% of their allocation from PFC – he was advised to stop home treatment and make use of cryoprecipitate by Dr Bolton (SNBTS) [**PRSE0003044**]. Dr Brian McClelland (SNBTS) gave evidence that Professor Ludlam brought an interventionalist approach to haemophilia treatment in Edinburgh, by which he meant the treatment of inhibitors, joint surgery and home therapy which required enormous amounts of concentrate.

114. Several of the witnesses who attended the Lord Mayor Treloar College told the Inquiry that they were put on prophylactic treatment in the mid-1970s. The headmaster gave evidence that he was aware that Dr Rainsford was conducting research into prophylactic treatment. In March 1984, Dr Aronstam refused to change the prophylaxis programme in response to AIDS [**TREL0000343_044**].

115. In a letter to Dr Colvin in April 1979 [**BART0002487]**, Dr Kernoff expressed an interesting take on the reasons for the exponential increase in the use of commercial concentrate:

> "*The principal reason for this increase is that until commercial concentrates became available in the last few years the demand for factor VIII was* ***artificially suppressed by the limited availability of supplies****. Now that such concentrates are available increasing numbers of patients are being treated, in accordance with modern practice, much more aggressively than has hitherto been the case.*" [emphasis added]

116. Interestingly, both Dr Colvin and Professor Tuddenham confessed to expending NHS concentrates on home treatment programmes and using commercial concentrate in the hospital. Dr Pettigrew stated that Dr Willoughby instituted prophylactic home treatment which meant that patients received more concentrate.

117. The medical records of the patients of Professor Bloom and Dr Mayne commonly include reference to a patient developing an inhibitor and the dosage of FVIII being increased to "treat" it. Questions remain as to the appropriateness of treating patients with inhibitors in this way. Dr Morris McClelland noted in his evidence that Professor Mayne seemed to have a high number of patients with inhibitors.

118. Dr Walford stated in evidence that in 1979 the NBTS wanted a handle on the purchase of imported product on safety grounds and discussed central purchasing but the HCDs were against it on choice grounds. In the event, the DHSS deferred to the views of the UKHCDO. The UKHCDO meeting in September 1981 Strongly resisted the suggestion by DHSS that RBTCs should purchase, hold, distribute, and control stock of all blood products [**LOTH0000012_122**]. Dr Kernoff was one clinician who expressed his vociferous opposition to losing control over the choice of product in a letter to Professor Bloom in September 1983 [**OXUH0000886_002**]. In that letter, Dr Kernoff refers to the desire of DHSS to reduce supply of commercial concentrates to reduce expenditure and states that it "*would in general be against the interests of haemophiliacs*" – an unjustifiable statement in light of knowledge at the time.

Clinicians turned a blind eye to the serious risk presented by imported concentrates and the Government failed to intervene

119. Dr Mark Winter confirmed that, notwithstanding that he knew in 1975 that 45% of irregular liver tests were attributable to NANB, there was an unwillingness

on the part of clinicians to see NANB as a serious problem because of the benefits of concentrates. He explained that from the mid-1970s onwards home treatment and concentrate usage continued to grow. By 1979 he accepted that clinicians ought to have known that NANB carried with it a risk of serious liver disease and should have advised their patients of the same. He stated that he could not remember telling patients about the risk of cirrhosis. He accepted that clinicians did not want to see the risk and that it was understated at the time. Thus, it is more likely that such a failure is attributable to a conflict of interest on the part of clinicians, rather than attributable to a general paternalistic approach in medicine at that time. As submitted below, clinicians continued to advise against a reversion to cryoprecipitate when the risk associated with AIDS was known. It is likely that this was caused by a conflict of interest. Therefore, it would be consistent with the approach taken in 1983 that from 1979 patients were not told about the risk of serious liver disease because clinicians did not want them to revert to cryoprecipitate use.

120. Dr Al-Ismail gave important evidence about Professor Bloom's practice and his own practice in the Swansea Haemophilia Centre. Professor Bloom knew in 1975 that NANB was "*potentially dangerous*" and stated so in a letter regarding a patient's home treatment as early as February 1975 [**WITN0047002**]. Professor Bloom also told Dr Al-Ismail about the Preston biopsy study. Professor Bloom discussed the World in Action documentary with him and explained that haemophiliacs knew the risks they were taking. Professor Ludlam, who worked as a senior registrar under Professor Bloom between 1975 – 1979, stated that Professor Bloom discussed with him the Bournemouth hepatitis outbreak in 1974 which was investigated by Dr Craske.

121. Dr Colvin also accepted that he would have been struck by Dr Craske's report in 1978 on the biopsy studies in the USA [**CBLA0000831**] in addition to Dr Preston's research, and the letter to him from Dr Kernoff on April 1979 in which Dr Kernoff stated that commercial concentrates carried a higher risk of transmitting NANB, "*a serious disease with long-term consequences*"

[**BART0002487**]. However, Dr Colvin explained that clinicians did not think that restricting concentrates for use in life-saving treatment was possible and that the advantage of cryoprecipitate for infrequently treated patients was not properly considered. It is submitted that, to the contrary, infrequently treated, or untreated patients were used to test the infectivity of commercial concentrates.

122. Dr Christine Lee also accepted that in an ideal world, clinicians should have known by 1979 that NANB was a clinically significant condition with a significant risk of disease. Professor Tuddenham accepted that by 1978 he was aware that NANB was a clinically significant condition with serious long-term consequences.

123. Dr Dempsey gave evidence that, when he arrived at the Children's Hospital in Belfast, cryoprecipitate was exclusively used. He stated that Dr Mayne and Dr Bridges discussed with him the risk of NANB and its association with liver disease in 1978/79. However, in 1981 Dr Dempsey started using commercial concentrates on children and did so until July 1983 when he stopped in response to the emerging information in relation to AIDS. So, on his evidence, he started using commercial concentrates on children when the seriousness of the risk of NANB was known and at a time when the common practice across the UK was not to use commercial concentrates on children – not even Professor Bloom advocated that. His justification was twofold: (i) that his confidence is cryoprecipitate was shaken due to one incident when it didn't stop an internal bleed in 1981; and (ii) Armour and Hemofil were keen to assuage any concerns he had in relation to the safety of their products; they stated that they had implemented a testing regime and had tightened up on donor selection and given those re-assurances, so was disposed to look favourably on their products. Further, notwithstanding that Professor Bloom continued to advise that the benefits of commercial concentrates outweighed the risks in July 1983, something prompted Dr Dempsey to cease the use of concentrates on children. This treatment regimen is all the more perplexing

when one considers that Dr Dempsey had available to him SNBTS concentrate, which he started using in July 1983. He confirmed that the supply of SNBTS concentrate was sufficient for his needs, so it is difficult to understand why he used commercial concentrate when SNBTS concentrate was available and in sufficient supply.

124. The picture that emerges from the evidence of the clinicians as to their response in 1979 to the knowledge that NANB could give rise to serious long-term consequences is that they took no notice of the earlier pleas of the DHSS and CMO-E to use commercial concentrate restrictively, even though they now knew not only of the higher incidence of NANB but also of the serious consequences. In other words, clinicians did not play their part to achieve self-sufficiency in blood products even though they knew of the potential consequences for patients resulting from viruses in commercial concentrates.

125. By September 1980 it is well-established that DHSS knew that NANB "*can be rapidly fatal…or can lead to progressive liver damage*" [**WITN0282008**]. So, DHSS knew that the increased risk posed by imported concentrates related to a risk of death or serious liver disease. No reasonable decision maker, on acquiring that knowledge, could fail to revisit: (i) the question of suppressing the use of home treatment; and (ii) the establishment of arrangements with PFC to fractionate plasma from England and Wales. However, Dianna Walford told the Inquiry that the DHSS was not paying attention to NANB in the way it should have been between 1979 – 1983.

126. Lord Clarke accepted that the DHSS had a responsibility to ensure that treatment provided through the NHS was safe and that clinicians were employed by the NHS for which the DHSS was responsible.

127. Indeed, this is borne out by the fact the Regional Health Authority ('RHA') with responsibility for the RTC in Belfast made arrangements with PFC in 1981. The decision-makers in Northern Ireland reacted albeit belatedly to the developing

knowledge about the risk posed by imported concentrates. The reasons why self-sufficiency was not achieved in Northern Ireland relate to a failure of execution and, in essence, a failure to suppress the increasing use of concentrates in home treatment programmes, therefore demonstrating that both (i) suppression of home treatment; and (ii) arrangements with PFC, were required.

128. Dr Winter accepted that the results of the testing for HIV done by Dr Kernoff on stored samples from 1979 and 1980 (which were negative) demonstrated that HIV was transmitted by concentrates after this date – so the response to the knowledge of serious liver disease is highly material to the later HIV infection. He concluded that had the policy of self-sufficiency established in 1974 worked, clinicians in England and Wales would have been using low risk concentrate, like those in Scotland, and the incidence of HIV amongst the haemophiliac population would have been in the region of 10% rather than 90%.

129. Lord Fowler also supported this view and told the Inquiry that the crucial failure was in the 1970s because had Lord Owen's advice been followed, much of the ensuing tragedy could have been avoided and the outcome would have been very different.

130. Although it is certainly correct to say that there was a failure to apply the precautionary principle to decision making about blood and blood products, that failure is beside the point. The real failure is the failure to act upon the knowledge that existed as of 1979 that blood products were dangerous. The point developed below is that this failure occurred because of conflicts of interest and a failure to act in the best interests of the patients – it was not in truth a failure to apply the precautionary principle but something more egregious. The precautionary principle is more relevant to the decisions that were being taken in the mid-1970s when it was known that imported

concentrates carried a higher risk of NANB, but the long-term consequences were less understood.

The arrival of AIDS in the UK, the failure to react in a timeous manner and the role clinicians in that failure

131. Dr Mark Winter accepted that between July 1982 and December 1982 clinicians should have been concerned that AIDS was transmissible by blood. He stated that he adopted a policy of not using concentrate unless the patient "*absolutely needed it*" for serious bleeding, trauma, or major surgery. He may have suspended prophylaxis.

132. Dr Dempsey accepted that he was in no major doubt from the end of 1982 that AIDS was transmissible by blood and blood products as the other theories "*did not hold water*". However, he stated that the haemophilia community were not prepared to commit themselves to the idea that AIDS was related to blood and blood products.

133. Dr Morris McClelland stated in evidence that he discussed the MMWR report with Dr Mayne in 1982.

134. Professor Tedder accepted that he would have associated the transmission of the virus causing AIDS with the transmission of HBV in June 1982 and he would have been of the view by then that AIDS was caused by an infectious agent that was transmissible by blood and blood products [**RLIT0001690**].

135. In December 1982, Dr Craske wrote to Dr Lane in advance of a Hepatitis Working Party meeting to send him a copy of a paper on AIDS in the USA he had prepared for the MRC Hepatitis Vaccine Group, in which he refers to 8 cases in the USA in haemophilia A patients and two non-haemophiliac cases which may have been related to transfusions 12 to 18 months previously [**CBLA0001653_001**].

136. Then, by 24 January 1983, following the meeting at Heathrow between Immuno Ltd, HCDs and Drs Craske and Zuckerman, chaired by Professor Bloom, there can be no doubt that the Public Health Laboratory Service ('PHLS') and HCDs were aware that AIDS was transmissible by blood products, that it had an incubation period of 6 months to 2 years and that it had a 45% mortality rate [**RFLT0000050 / PRSE0002647**]. A number of important submissions flow from this meeting:

a. As has been explored with several witnesses during the Inquiry, the 10 deaths amongst haemophiliacs in the USA did not indicate that the risk of transmission was low, precisely because the clinicians knew about the latency period;

b. No reasonable clinician would have continued to use imported concentrates in light of the knowledge gained at this meeting;

c. At the very least, informed consent should have been obtained from patients but the weight of the evidence from the infected and affected is that they were not informed of the risk;

d. Notwithstanding the above, the meeting concluded in an agreement to carry out further studies of the infectivity rate of Immuno's concentrate on adults who were susceptible to NANB infection – in other words, PUPs – before moving on to trials in children;

e. The magnitude of the failure of clinicians to act on this information probably explains why so many of them claimed to have no recollection of this meeting[3]. It is inherently unlikely that so many clinicians who were in attendance have no independent recollection of such a profound meeting and their claim to the contrary must be taken to affect their credibility on the central issue of their knowledge of the risks associated with NANB and AIDS and whether they obtained informed consent and/or took all reasonably practicable steps to minimise the risk of death to their patients; and

[3] Dr Colvin claimed to have no recollection ; Professor Tuddenham recollected only the discussion about T48 ratios.

f. Any administration of imported concentrates from January 1983 onwards, in the absence of informed consent, was grossly negligent / reckless.

137. There was a CBLA meeting on 23 March 1983 [**CBLA0001690 / CBLA0001691**] at which Professor Bloom informed the meeting of the reports in the USA and the high mortality rate but stated that the aetiology was unknown. He suggested that AIDS should be discussed at a future meeting (20 April 1983). Dr Lane noted in the memorandum following the meeting that patients in the UK were evidently concerned and the resistance to imported concentrates was becoming apparent. He then discussed the potential role of BPL in producing cryoprecipitate on a short-term basis. Dr Lane prepared a further memorandum following the meeting on 20 April 1983 [**CBLA0001697**] and stated that it had been decided to take a "*wait and see*" approach and that large-scale cryoprecipitate production had been ruled out on logistical grounds. Professor Bloom is said to have stated that CDR reports give no evidence of AIDS in haemophiliacs, notwithstanding that on 26 April 1983 he informed Dr Craske of a "*probable*" case of AIDS **[WITN3408009].** Thus, it would appear that at these meetings Professor Bloom was not giving full and frank disclosure to the CBLA.

138. It did not require any prophetic powers to realise the importance of ceasing the use of imported product. It is unclear why it took PHLS another 3 months to recommend that all imported concentrates should be withdrawn from use on 9 May 1983 [**CBLA0000043_040**]. On the face of it, that delay in blowing the whistle is unjustifiable, given the magnitude of the risk. It is very concerning that Dr Galbraith's letter to the Biological sub-Committee of the Committee on the Safety of Medicines ('CSM-B') was not acted upon by the members of that sub-committee, some of whom were present at the Heathrow meeting. Sir Michael Rawlins, who was a member of CSM, gave evidence that when they met to discuss the advice of the CSM-B in July 1983 they should have been provided with a copy of Dr Galbraith's letter and had they been, he would have

hoped that they would have made a different decision; had they known it was a virus and how frequently pooled donors in the USA had the virus, the CSM **would** have done something differently. He accepted that "*obviously*" the CSM failed to recognise and respond to the viral risks from pooled plasma.

139. Professor Tuddenham opined in evidence that this letter should have been shared with the HCDs and that he agreed with Dr Galbraith that the incidence of AIDS did not reflect the risk – that was "*fundamental epidemiology*". Professor Ludlam also stated that this letter should have been brought to the attention of HCDs. He accepted that by early 1983 he realised that concentrates contained a risk of HIV.

140. Dr Walford also told the Inquiry that this letter was not brought to her attention. It really is a lamentable failure of the administration within the DHSS at that time that such an important letter, written by the Head of the CDSC, was not brought to the attention of SMOs. The blame must really rest with not only Professor Bloom, but also Dr Rejman who was the conduit for the exchange of information. In his evidence, Dr Rejman attempted to absolve himself of responsibility on the basis that the SMO with responsibility for hepatitis should have raised it further up the chain. The Public Health Administration Expert Group stated that it is tantamount to misleading a Minister by not telling them of a dissenting view within an expert group – the Minister needs to consider the reasonable range of opinions.

141. What is more, it is unacceptable that the involvement of the CMO-E in the issue of blood and blood products depended on the personality of the person holding that office. The Inquiry heard from a number of Secretaries of State and Ministers who drew comparisons between Sir Henry Yellowlees and Sir Donald Acheson. No explanation has been provided why the CMO-E or their team of SMOs did not follow up on the correspondence that was sent in 1975 on the issue of self-sufficiency because of what was known about the risk associated with imported concentrates even at that time. The knowledge of the

seriousness of the risk developed, as accepted by Dr Walford, but the impression gleaned from the evidence of the SMOs is that they absolved themselves of responsibility for the safety of the supply of blood and blood products on the mistaken justification that the freedom of the clinician is sacrosanct – that simply will not do in the context of a known public health risk.

142. Lord Clarke made a rare concession when shown Dr Galbraith's letter. He admitted that he did not know about the long incubation period, that the letter should have been seen by Ministers and if had been, thousands of lives could have been saved – the import being that a Ministerial decision would have been taken implementing Dr Galbraith's recommendations. He said that the decision should not have been left to the CSM-B. Lord Fowler agreed with that analysis and also stated that had the CSM-B agreed with Dr Galbraith's letter, that would have had a profound effect. He stated that the letter should have gone to the CMO-E.

143. The Q&A sheet at [**HSSG0010056_035**] which is apparently dated 3 May 1983 is an interesting document. It contains the mortality rate of 40% which is presumably information obtained from the Heathrow meeting. It also discussed the suspected case of AIDS in one of Professor Bloom's patients in Cardiff and stated that since 1980 the patient had not received imported concentrate, only NHS concentrate, so that although the imported concentrate could not be excluded as the cause because of the long incubation period, "*it is not possible to know whether British concentrate may contain AIDS agent*". Whilst it may be correct to say that it was not possible to exclude NHS concentrate as the cause, that rather looks like an attempt by Professor Bloom to deflect finger pointing away from imported concentrates, even though he had been at the Heathrow meeting.

144. The Welsh Office convened a meeting on 4 May 1983 to discuss the implications arising from the reported case of AIDS in Cardiff [**HSSG0010055_001**]. Present

were the CMO-W (Dr Gareth Crompton) and three medical officers from the Welsh Office, Dr McEvoy from the CDSC (the same organisation as Dr Craske who had received the report of "*probable AIDS*" on 26 April 1983 [**WITN3408009**]), a representative from the health authority Dr Napier and Professor Bloom. The minute records that Professor Bloom admitted that the Cardiff case was consistent with AIDS. There was pressure from the press in days leading up to the meeting. The minutes record that a suggestion that with foresight and sufficient expenditure, reliance on imported concentrates could have been avoided was "*based on a false premise*". It was stated that "*it was important to keep the problem in perspective*" and that the problem in the USA was due to: (i) an increase in the use of blood and blood products; and (ii) prevailing homosexuality and drug use. It then stated that if imported concentrates were banned, that would halve the available concentrate and then:

> "*Blood product laboratories in the UK are presently working to capacity. If we were in Wales to attempt locally to make good on our own deficit it would require a great deal of extra facility within the NBTS at Rhydlafar. It follows that a ban on imported factor 8 would necessitate:*
> *a. A reduction in patients treated;*
> b. *The modification of the home treatment facility (with the associated consequences of lost jobs with implications for social services as well as for the health service.*
> …
> *The asserted greater risk arising from the use of purchased blood as opposed to voluntary donated blood is less than hitherto with the greater awareness of the AIDS problem…there is no justification on the basis of facts so far established to ban the importation pf factor 8 though it was thought preferrable in the case of children to restrict treatment to the BPL concentrate produced in Britain.*"

145. The advice given to the Welsh Office at this meeting was misleading and/or grossly negligent and/or reckless for the following reasons:

    a. As discussed by DHSS and CMO-E as early as 1974, it was foreseen that blood products carried a risk to health and with sufficient expenditure and/or arrangements with PFC, self-sufficiency could have been achieved;

b. Blood laboratories in the UK were not working to capacity – this statement misleadingly omits the fact that PFC did have potential to fractionate Welsh plasma;
c. It would not have required additional capacity within the NBTS at Rhydlafar – arrangements could have been made with PFC;
d. A ban on imported concentrate would not have led to a reduction in patients treated – rather, it may have led to a reduction in the amount of home treatment / prophylaxis;
e. The loss of jobs at the home treatment facility and consequences for social services and health service could hardly override the risk of death to patients treated with imported concentrates;
f. Dr Tony Napier stated in evidence that Cardiff RTC did start producing more cryoprecipitate in response to the developing knowledge of AIDS;
g. It is plainly wrong to suggest that the risk presented by imported products as compared with domestic products was less. Presumably, this was based on the fact that the 'Cardiff patient' used NHS concentrate between 1981 and the onset of symptoms in December 1982. However, Professor Bloom had been told by Immuno Ltd that the incubation period was up to 2 years – so the facts were entirely consistent with infection from commercial products in 1980/81;
h. Dr Tony Napier stated in evidence that around this time, it was the common view that AIDS was a virus transmissible by blood and blood products;
i. The statement that "*there was no justification*" to ban imported concentrates was unreasonable – 5 days later Dr Galbraith wrote to the CSM-B suggesting exactly that – it is unclear why Dr McEvoy did not correct that statement at this meeting. The then incidence of AIDS amongst haemophiliacs in the UK did not represent the risk and Professor Bloom must have known that, given what he was told at the Heathrow meeting;

j. There is no evidence that Professor Bloom updated those who attended this meeting 4 days later when he received Dr Galbraith's letter on 9 May 1983 in his capacity as member of the CSM-B.

146. This was a missed opportunity for the Welsh Office to discuss putting in place arrangements for PFC to fractionate plasma from Wales. There seems to have been no discussion or collaboration with their counterparts in Scotland or Northern Ireland, otherwise PFC would surely have been discussed at the meeting. It is regrettable that the CMO-W was not in a position to advise on the points identified above and the Inquiry has received no evidence as to whether the Welsh medical officers liaised with their counterparts in the other four nations. In other words, it may well have been that the CMO-W was entirely reliant on Professor Bloom for accurate advice – the same person who later advised CSM-B and UKHCDO to the same effect whilst dishonestly suppressing the knowledge that he acquired in relation to AIDS from January 1983.

147. The advice that went to the Minister following this meeting [**HSSG0010055_002**][4] is misleading in additional ways:

a. It stated that there is no proven connection between the 'Cardiff case' and the use of imported Factor VIII, even though for the reasons explained above a link could not be excluded and it was more likely that the transmission was from USA blood products rather than UK blood products given the higher prevalence of AIDS in the USA at that time, which Professor Bloom knew about;

b. It stated that the level of risk created by imported blood products was "*very small*" and there was no cause for precipitate action. There was no proper basis for Professor Bloom describing the risk as very small.

[4] The end of this note refers to information received from DHSS that the Minister was due to meet with the Haemophilia Society – this is one of very few references in the evidence to an exchange of information between the Welsh Office and DHSS.

148. Therefore, had this meeting identified the potential to send plasma to PFC to be fractionated (there was never a shortage of plasma in Wales and a plasmapheresis scheme was not discussed) and had arrangements been put in place, the incidence of HIV in Wales may have been reduced as patients would not have been exposed for the whole period between May 1983 and the introduction of BPL 8Y in 1985. SNBTS knew what would have been involved in such arrangements, as they had already been put in place with NIBTS.

149. All of that should be contrasted with the letter sent by Professor Tedder on 20 May 1983 to Dr Walford in which he stated that the epidemiology of AIDS "*bears a striking similarity to hepatitis B*". He stated that "*since the evidence is that [AIDS] is becoming established in the UK*" and considered it was likely that the aetiological agent causing AIDS was a virus "*since FVIII is implicated*" [**DHSC0003824_164**].

150. Against that background, it is utterly astonishing that on 13 July 1983 Professor Bloom continued to advise the CSM-B, in response to Dr Mortimer stating that an infectious agent was likely and Dr Galbraith advising that haemophiliacs were at risk (in his capacity as Head of the Communicable Disease Surveillance Centre), that the benefits of imported concentrates continued to outweigh the risks so that there was no need to alter the licence conditions and the matter should be left to clinical judgment [**DHSC0001209**]. He justified the conclusion that USA concentrates should not be withdrawn on the basis that: (i) it would be impossible to meet needs; (ii) even if needs could be met it would involve a major rethink of UK policy; and (iii) the perceived level of risk did not justify this response. The fundamental flaw with this analysis is that 'need' is based on usage including home treatment, whereas 'need' could have been interpreted more narrowly in response to the risk of death posed by the imported concentrates. Professor Bloom acknowledged in his litigation report

written in 1990 that a reversion to cryoprecipitate would have resulted in a cessation of home therapy [**DHSC0001297** at p90][5].

151. This advice effectively meant that the body who could have imposed conditions on imported blood products or indeed banned them – the CSM on behalf of the Licencing Authority – were not provided with the relevant information in relation to risk – Sir Michael Rawlings confirmed as much in his evidence.

152. Even more astonishingly, as late as October 1983 Professor Bloom, in his capacity of chair of the UKHCDO, advised clinicians to resist the demand by patients for a change from imported concentrates to cryoprecipitate on the basis that there was no need as there was no proof that they caused AIDS [**HCDO0000003_051**]. This advice was nothing other than disingenuous. At the very least, it amounted to a material non-disclosure of the knowledge that he had acquired in the preceding months.

153. Even Dr Colvin, who did not concede very much in evidence, thought Professor Bloom was guilty of "*wishful thinking*" at this point and it was surprising that the UKHCDO did not make stronger recommendations. The reality is that it was far more than wishful thinking – it was deliberately misleading. Professor Franklin stated that Dr Galbraith's letter should have led to a high-level direction to all HCDs. Dr Al-Ismail gave evidence that Professor Bloom told him in August 1983 that he did not think that AIDS was going to be a big problem in UK haemophiliacs and that he did not discuss the San Francisco baby case with him following the Heathrow meeting. He stated that he followed the advice of Professor Bloom and that "*we erred on the side of optimism during the outbreak of AIDS*".

[5] Interestingly, when listing the developments in January 1983 in relation to the knowledge of AIDS in that report, Professor Bloom did not refer to the Heathrow meeting.

154. However, the implication from those clinicians, who claimed that they should have been told about Dr Galbraith's letter, that they otherwise did not know about the risk should be rejected outright. A number of them were present at the Heathrow meeting with Dr Craske from PHLS when the knowledge was acquired. The reality is that they were all complicit in their silence and allowed Professor Bloom to provide misleading advice without challenging it or speaking out.

155. The justification wheeled out by several clinicians, politicians, and civil servants that concentrates was "*life-saving treatment*" has been effectively undermined by the Inquiry. In rare cases, a serious bleed may require concentrate and there is no dispute about that. Counsel to the Inquiry put to many witnesses that the use of concentrates should have been restricted in that way rather than it becoming and remaining normal treatment in response to a bleed or prophylactically. Professor Hay accepted that the introduction of cryoprecipitate led to an increase in life expectancy and that life expectancy doubled between 1969 and 1974 [**PRSE0004645**] at a time when cryoprecipitate was the treatment of choice and there was no home therapy. He further accepted that there was only a modest increase in life expectancy with the advent of concentrates and there was no increase in the proportion of deaths attributable to intracranial bleeds.

The conflict of interest at the epicentre

156. In order to understand why Professor Bloom *et al* favoured clinical freedom over taking reasonable measures to mitigate the risk of death, it is necessary to understand the conflict of interest that existed.

157. It was the *modus operandi* of the pharmaceutical companies to ingratiate themselves with clinicians and patients alike. Dr Mark Winter gave evidence that he once too 100 children to Disneyland Paris, a trip funded by the commercial companies. Those companies also funded residential weekends for

adult patients. He contrasted that with BPL who did not fund that type of activity.

158. Furthermore, as identified by Dr Christine Lee in her evidence, if the clinicians chose the commercial concentrate "*there was a great deal of profit to be made*" in that an NHS Trust would purchase the product at a bulk price and distribute it on with a mark-up. She also accepted that Dr Kernoff's research was funded by pharmaceutical companies.

159. Professor Tuddenham accepted that the commercial incentive overwhelmed safety issues. The money being spent by commercial companies on lavish entertainment created sub-conscious bias [if not conscious bias]. Professor Tuddenham was a consultant at Speywood Laboratories and purchased their products for use at his hospital.

160. Dr Vivien Mitchell referred to receiving expenses from Cutter to attend a conference in Milan in 1986 and that she heard stories of first-class flights etc. Dr Pettigrew was funded by Armour to attend the World Haemophilia Meeting in Rio de Janeiro.

161. We know from correspondence that Professor Bloom was flown first-class to the USA with his wife for a conference and a meeting with a pharmaceutical company.

162. Professor Bloom's approach between January 1983 and July 1983 demonstrates that he acted unreasonably and was likely to be unduly influenced by pharmaceutical companies. This also explains his approach prior to 1983 and his role in the failure to achieve self-sufficiency in that he was instrumental in increasing the demand for imported concentrates both to enable home treatment programmes and in his treatment of inhibitor patients[6] – an approach

[6] There are many examples in the notes of Professor Bloom's patients where he refers to a patient developing an inhibitor to FVIII.

also adopted by Professor Mayne. Professor Hay stated in evidence that the UKHCDO received funds from pharmaceutical companies to carry out research into inhibitor patients. His role in creating this exponential increase in the demand for imported concentrates, notwithstanding the fact that the DHSS and CMO-E wished to suppress this demand, is consistent with his approach post-January 1983 – on both occasions he was taking an approach which was inconsistent with the best interests of patients that resulted in expensive imported concentrates being purchased in great quantities.

163. Professor Bloom's duplicitous conduct extended to his dealings with the Haemophilia Society. Firstly, not only was Professor Bloom advising Government, but he saw no issue with advising patients at the same time with the result that there was no challenge to his advice. Secondly, medical advisory panel members for the Haemophilia Society were not questioned about potential conflicts of interest and Professor Bloom had a say on who joined it – David Watters described it as very nepotistic. Thirdly, based on Professor Bloom's advice, the Haemophilia Society decided to lobby Government against the ban of imported concentrates on 9 May 1983 – 5 days after Professor Bloom advised the CMO-W and the same day that Dr Galbraith sent his letter to CSM-B [**BPLL0001351_076**]. The Haemofact for September 1983 advised readers that the risk of AIDS was "*tiny*" [**PRSE0000088**].

164. Ultimately, Dr Winter concluded that UKHCDO took a wrong turn in relying on the principle of clinical freedom and that DHSS should have put more formal advice and restrictions in place. The inference from his evidence is that he recognised that clinicians' decision making was compromised, and they were not best placed to make the decision on whether imported concentrate should be used.

165. The cosy relationships with pharmaceutical companies also played out in the resistance of clinicians to relinquish control of the selection of commercial concentrates – the justification that the clinicians had intimate knowledge of

the product has not been established during the Inquiry. A commercial product was either licenced, or it was supplied outside of the licencing regime on a named-patient basis at the request of pharmaceutical companies.

166. Professor Parapia gave evidence that in 1982 he ordered commercial concentrate largely for home treatment, even though he always had a sufficient supply of NHS concentrate (see also [**PARA0000015**]) – he purchased commercial concentrate only because it was convenient. He had no clinical justification for purchasing commercial concentrate – even on the needs-based approach adopted by other clinicians. Yet he candidly accepted that he accepted hospitality from commercial companies.

167. His evidence is quoted at the beginning of these submissions. The purpose of lavish hospitality was to influence clinicians and we can see it worked to the detriment of patient safety. Some of those clinicians advised Government, did not provide independent advice, and did not declare their interests. The first time that the UKHCDO required declarations of interest was 1993[7]. The inappropriate relationships between pharmaceutical companies and clinicians were the pervasive rot that led to the collapse of good clinical decision-making in haemophilia care and impartial advice to Government.

168. Dr Bevan, like Professor Parapia, gave evidence that the pharmaceutical companies still pay travel and hotel costs for international conferences today.

169. Professor Collins, who is the HCD at Cardiff today, explained that he approached pharmaceutical companies to make a donation, some of them donating between £10,000 - £20,000 which was put into an endowment fund. He accepted that the potential risk of pharmaceutical companies influencing product selection still exists today in many areas of healthcare.

[7] Dr Giangrande.

170. The conflict of interest even extended to the CSM. Sir Michael Rawlins confirmed that members of the CSM did not have to declare conflicts of interest. He opined that colleagues were put under pressure by payments received from pharmaceutical companies. He stated that he was concerned about the sponsorship that pharmaceutical companies provided for clinicians to attend conferences. In an article entitled "Bribery" published in the Sunday People in March 1981 [**JEVA0000125**], Sir Michael stated that "*there is a certain amount of covert **bribery***". He referred to pharmaceutical companies paying expenses for foreign conferences and stated that he had also been invited. He also stated:

> "*The companies are not idiots. They would not do it if it was not worthwhile…education gets mixed up with financial rewards or other substitutes.*"

171. Importantly, he stated that he wanted the Royal College of Physicians to end excessive hospitality and increase transparency.

172. The Public Health Administration Expert Group told the Inquiry that the Nolan principles on standards in public life (selflessness, integrity, objectivity, accountability, openness, honesty, and leadership) apply to anyone in public life, including NHS staff. That includes clinicians and the members of the CSM. The actions and inactions identified above breach every single one of Nolan's seven principles.

Regulation of Blood Products

173. Many of those were infected by commercial concentrates which were licensed by the Licensing Authority. This calls into question whether those responsible for licensing blood products in the 1970s and 1980s took proper consideration of the relevant factors set out in section 19(1) of the Medicines Act 1968.

174. There were also patients who received un-licensed products on a 'named-patient basis', meaning that the product licensing requirements were by-passed by clinicians when prescribing blood products.

175. This section will cover the decisions made by the following bodies which were responsible for the regulation of medicinal products from the 1970s to the 1990s:

a. The Licensing Authority (1979-1989);
    i. The Medicines Division of the DHSS; and
    ii. The Statutory Committee on the Safety of Medicines ('CSM') and the CSM Sub-Committee on Biologics ('CSM(B)');
b. The Medicines Control Agency ('MCA') (1989-2003); and
c. The National Institute for Biological Standards and Control ('NIBSC') (1972–).

176. Further, this section aims to consider the state of medicinal regulation today, and what recommendations the inquiry could and should make.

Findings of Fact – 1970s

177. We ask that the inquiry make the following findings of fact:

a. The bodies responsible for the regulation of blood and blood products failed in their statutory duties;
b. The bodies responsible for the regulation of blood and blood products failed to keep patients safe;
c. The decision(s) to grant licences for commercial concentrates were irrational;
d. There were insufficient controls to guard against conflicts of interest within the Licensing Authority, the CSM, and its various sub-committees;
e. Those responsible for granting or refusing licences failed to impose conditions on licences which may have protected patients;

f. Those responsible for granting or refusing licences failed to recognise that patients are its raison d'etre;
g. There was a distinct lack of vigilant, long-term monitoring;
h. There was an underestimation of the seriousness of HBV; and
i. The reporting systems in place to deal with emerging health risks were wholly inadequate.

178. An illustrative example of some the above failings can be found in the Licensing Authority's decision to grant a licence for Hemofil in February 1973.

179. On 24 October 1972, Dr Duncan Thomas (senior medical officer for CSM(B) from 1971 to 1974) visited Hyland Laboratories, Costa Mesa, California. He noted that the blood bank in downtown Los Angeles received "*regular customers*" who "*needed*" money. The medical screening was "*rudimentary*". The pooled plasma contained plasma of as many as 6,000 donors. He concluded "*obviously the main problem with this product is the hepatitis hazard. The donors do not inspire confidence, and Factor VIII concentrate is prepared from very large plasma pools. Despite the HAA testing, the risk for hepatitis must still considered to be present.*"

180. What Dr Thomas at Hyland saw would later be described as "*in conformity*" with what can be seen in the World in Action documentary broadcast in December 1975. The only reasonable conclusion to draw was that Hyland's practices gave rise to a significant risk of injury to recipients of their blood products. This is not a point which can only be made with the benefit of hindsight, as alleged by Dr Thomas in his witness statement to the inquiry. In 1975, the producers of the documentary, and many of those who saw it, were aghast at what was found at Hyland. In his witness statement, Professor Hugh Tunstall-Pedoe comments that he was "*amazed*" that the NHS had gone to the USA for blood products. Further, Dr Brendon Grey's evidence was that the risks of transmission of hepatitis through factor concentrates were recognised

form the time of first supply. Yet, the CSM(B), having read Dr Thomas's report, recommended that a licence be granted.

181. Dr Thomas's report was considered by the CSM(B) on 10th January 1973. The meeting was confidential. The medical comment stated:

> *"The major disadvantage of currently available commercial preparations, such as HEMOFIL, is that they are prepared from very large plasma pools, and carry the risk of transmitting hepatitis virus. Hyland screen all their donors for hepatitis-associated antigen, which reduces but does not eliminate this risk. However, no attempt is made to disguise the risk for hepatitis, and it may be considered that the decision to use this material could be left to the individual clinician who can balance the potential hazard against the anticipated therapeutic benefit to the patient. It is recommended that a product licence be granted."*

182. It is not clear why the fact the company made no attempt to disguise the risk of hepatitis should be considered a positive. It is perhaps even more concerning that, knowing the risk of viral hepatitis, the company continued to fractionate plasma in very large pools. The inquiry has a comprehensive chronology on Knowledge of Risk. We do not intend to repeat the contents. However, when considering this report in light of that chronology, it is clear that the risks of large pool sizes were known.

183. It has been said, particularly by Dr Thomas in his written statement, that the hepatitis referred to was HBV. We say this does not ameliorate the position. As the inquiry has heard, HBV is a serious and debilitating condition in its own right. Further, this does not deal with the point that NANBH was known about. It was at least known that post-transfusion jaundice was a common phenomenon. Any jaundice should have been considered serious and investigated further, as jaundice indicates liver damage.

184. Further, the CSM(B) appear to divest their responsibility to protect patients to clinicians when saying the risk-benefit analysis should be left to the individual clinician.

185. We say this was wholly inappropriate for a number of reasons:

a. Clinicians should be one of many safeguards within the blood transfusion chain;

b. The Licensing Authority is one of the layers of protection for a patient;

c. The Licensing Authority have a statutory obligation to ensure that licences are granted for products which are reasonably safe;

d. The Licensing Authority (or at least the various committees, sub-committees, and divisions of the DHSS) were better placed to provide a risk-benefit analysis of a pharmaceutical product than a clinician; and

e. In failing to either refuse to grant a licence, impose more onerous conditions on the licence, or issue "dear doctor" letters to clinicians about the risks posed by commercial concentrates, the Licensing Authority was tacitly confirming the safety and efficacy of those products.

186. In February 1973, the CSM received an application for a licence for Hemofil. The label appended to the application stated:

> "*Such plasma may contain the causative agents of viral hepatitis. There is no known laboratory test to demonstrate either the 'presence of the absence of such agents, and the concentrate has not been subjected to any treatment known to diminish the risk of transmission of hepatitis. […] The concentrate should, therefore, be used when its expected effect is needed in spite of the unknown hepatitis risk associated with its use. Special consideration should be given to the use of this concentrate in newborns [sic] and infants where a higher morbidity and mortality may be associated with hepatitis.*"

187. However, including the above warning in the leaflet does not absolve either the pharmaceutical company, or the Licensing Authority of blame. In the 1970s, in line with the practice at the time, information about the potential and actual risk was only included in the datasheet for physicians. No information was shared directly with the patient, relying on communication from prescribing physicians. Until the 1992 EEC Directive came into force, few medicines were supplied with leaflets.

188. In any event, we say that there are a number of inadequacies with this information leaflet. In particular, "unknown risk" is a misnomer. The risk was known and unquantifiable. Still, the CSM imposed no conditions concerning hepatitis warnings. Later, when risks became quantifiable, there was no condition imposed concerning the warnings. We say that the warning about hepatitis was wholly inadequate. Were the risks to be spelled out adequately, it may have become clear that such risks would be incompatible with the granting of a licence.

189. This example is illustrative of a number of matters:

a. Dr Thomas and the other responsible for regulating blood products knew about the risks of blood borne viruses but failed to either protect or warn patients of the same;
b. The Licensing Authority divested its statutory duty to clinicians;
c. The warnings concerning hepatitis were inadequate;
d. The CSM granted a licence in spite of the clear risks to patient safety;
e. The CSM failed to impose conditions on licences which may have protected patients; and
f. The CSM failed to recognise that patients are its raison d'etre.

190. Professor Sir Michael Rawlins in his evidence confirmed that CSM could have imposed conditions on the grant of a licence, including:

a. A requirement to provide a warning on the packaging and/or leaflet in perpetuity or until such time as an application to vary was made; and
b. To monitor therapeutic efficacy and safety and to report results to the Licencing Authority.

191. However, once the licence was granted, CSM appear to have taken no action to either revoke licences or strengthen conditions in line with the growing knowledge base concerning the risks of NANBH, and later HIV/AIDS.

192. Further, in relation to the reporting system, Professor Sir Rawlins's evidence was that doctors seeing hepatitis or jaundice should have reported the same to the CSM. It appears that this did not happen. This reveals a key failure in the reporting system. There was substantial underreporting of adverse effects of commercial concentrates. It appears that post-transfusion jaundice was seen as "just one of those things", something which was acute in nature only, rather than the warning it should have been of a much more serious problem. The inquiry heard evidence about a system which failed to identify promptly significant adverse outcomes arising from commercial concentrates. It is clear that there was gross under-reporting of the serious adverse effects.

Findings of Fact – 1980s

193. In the 1980s, partly due to the failings of the Licensing Authority in the 1970s, commercial concentrates were prolific. In July 1983, on the suggested agenda for CSM(B), was AIDS in relation to licensed blood products. Attendees included Professor Bloom, and Drs Galbraith and Gunson. We have made comments elsewhere in our submission about the behaviour of Professor Bloom, and the influence he appeared to exert in many areas of blood policy. Here, we see his influence again. The following conclusions (inter alia) were reached:

a. While the cause of AIDS is unknown, an infectious aetiology seems likely;
b. Patients who repeatedly receive blood clotting-factor concentrates appear to be at risk, but the evidence so far available suggests that the risk is small;
c. Balanced against the risks of AIDS are the benefits of blood clotting-factor concentrates' use; in the case of haemophilia, they are lifesaving; and
d. The possibility of withdrawing clotting factor concentrates (and/or US factor concentrates) from the market and replacing them with cryoprecipitate was considered but rejected on the grounds of supply.

194. The above demonstrates a common theme concerning decision-making during the AIDS crisis of the 1980s; the wrong test was applied to risk analyses. Words that are used repeatedly are "clear/conclusive evidence/proof [of risk]". The test should be inverted. Where there is some evidence of risk, the precautionary principle should apply until such time as there is clear/conclusive evidence/proof of a lack of risk. The CSM's decision making in relation to the risk of AIDS posed by commercial concentrates was irrational.

195. During the 1980s, the devastating effects NANBH also became more widely understood, even if there was no test for HCV at that time. Despite this, the CSM did nothing to alter conditions on grants, or to warn doctors.

196. CSM(B) failed to conduct an adequate risk/benefit analysis in relation to hepatitis or AIDS. Further, the adverse reaction subcommittee failed to furnish the biologicals sub-committee with any such analysis. Professor Sir Michael Rawlins's evidence was that this "would have been reasonably normal". Therefore, this was a system which was disjointed, siloed, unresponsive and defensive. The system failed to spot trends that gave rise to significant safety concerns.

197. The CSM did nothing by way of warnings to doctors, revoking of licences and/or imposing of conditions in response to the risk of hepatitis and AIDS. The only variations made were at the behest of the pharmaceutical companies making applications for variations. Often these were applications to vary which resulted in patients being exposed to a greater risk. The best example of this is the dispute which took place between February 1980 and January 1981 concerning the application to vary the licence for Humanate [**INQY0000411** at pp 16-17].

198. However, when it came to applications to vary product licences for products which were heat-treated, the CSM made the decision in respect of Hemofil-T to

refuse the licence because, inter alia, lack of justification for "*the inclusion and choice of heat treatment*". Here was a method which potentially made blood products safer than unheated concentrates (although we know in fact the heat treatment was not successful in inactivating HCV or HIV), yet the CSM refused to vary the licence. Meanwhile, the old product licence for non-heat treated Hemofil remained valid, and patients continued to receive commercial concentrates with no viral inactivation procedures at all. This was a trend which continued until 1985.

199. Throughout the 1970s and 1980s, no conflict-of-interest checks were undertaken in relation to potential members of CSM or its subcommittees. Members were expected to declare conflicts of interest, but there was no strict rule about it.

200. Further, it was not uncommon for treating clinicians to appear before CSM or its subcommittees to advocate on behalf of a commercial company.

201. We are concerned by conflicts of interest, whereby members of committees had financial and other links with the pharmaceutical and medical device companies. We say that these conflicts of interest at least call into question the dubious decision-making in the 1970s and 1980s concerning commercial concentrates and the risks they posed of infecting patients with blood borne viruses.

202. Finally, we ask where the NIBSC were in all of this. They are conspicuous by their absence and failed to protect patients.

What Has Changed?

203. Dame June Raine's evidence was that it would be hard to imagine or justify a circumstance where a blood product was licensed knowing that it would transmit a virus, however innocuous. This suggests, that had pooled factor

concentrates known to transmit NANB Hepatitis come before the MHRA (Medicines and Healthcare products Regulatory Agency) for licensing today, it would not receive a product licence.

204. However, there remains room for improvement, as can be seen from both the Cumberlege Review and the evidence heard by this inquiry. Recommendations for these improvements are dealt with elsewhere.

205. Turning to what has changed since the time periods covered above, during the 1980s, the Medicines Division of the DHSS frequently breached the product licence application timelines laid down by the EU, and by the mid to late 1980s serious concerns were raised about the ability of the Medicines Division to cope. In response, the Evans-Cunliffe Inquiry was established, and reported in December 1987. The Report recommended the reorganisation and restructuring of UK pharmaceutical regulation, including a shift from the existing part industry/part governmental funded model to model where the funding came solely from the pharmaceutical industry.

206. On 1 April 1989, the Medicines Control Agency (MCA) was established. The MCA was funded by fees for the processing of licences, and in 1991 it became an executive agency of the Department of Health, giving more financial freedom.

207. Then, in 2003, the Medicines and Healthcare products Regulatory Agency ('MHRA') was formed with the merger of the MCA and the Medical Devices Agency ('MDA'). In April 2013, it merged with the NIBSC.

208. The Independent Medicines and Medical Devices Safety Review was announced in February 2018. It was asked to focus on how the health system responds when patients and their families raise concerns about the safety of treatments. Baroness Cumberlege was asked to chair the review and to look at the cases of:

a. Vaginal mesh;
b. Sodium valproate;
c. Hormone pregnancy tests (HPTs).

209. The Review published its report on 8 July 2020 and made 9 recommendations. It is clear from reading this report that many of the concerns expressed above in relation to regulation of medicines were also held by Baroness Cumberlege.

210. As to the hemovigilance procedures in place today, the Blood Safety and Quality Regulations 2005 require manufacturers to report serious adverse events and serious adverse reactions to the Secretary of State. However, the extent of compliance with this obligation is unknown. The MHRA's enforcement powers have never been used, therefore it is difficult to see what incentive exists to encourage manufacturers to comply with their obligations.

211. Further, the Yellow Card Scheme allows for clinicians and patients to report suspicions that a medicine or blood product may have caused harm to a patient to the MHRA. However, this system is not designed to deal with adverse reactions which manifest months or years later. By 2005, patient reporting was established.

212. The yellow card system was and remains voluntary and not all clinicians use it to report adverse reactions so that there is significant under reporting through the yellow card system and there remains a risk today that trends will be missed unless the reporting system is made mandatory.

213. There is a striking similarity between the approach of the CSM to commercial concentrates and its approach to sodium valproate. As The Times article 'A scandal worse that Thalidomide' details [**RLIT0001623**] in 1972 / 1973 the CSM identified that sodium valproate was "*liable to cause abnormalities*" in foetuses but that "*the risk appears to be low, and not sufficient to justify stopping the use*" of the drug. The CSM decided against warning patients of the risk so as to avoid

causing "*fruitless anxiety*". Warnings were only to be provided to the clinicians and the use of the drug would be left to their discretion. The CSM failed to carry out any surveillance on the safety of the medicine. The Health Minister at the time told Parliament that CSM had concluded that "*there was no clear evidence*" that it was dangerous – there is a chilling resemblance between that phrase and "*no conclusive proof*".

214. Sir Michael Rawlins admitted in evidence that he could not say that the MHRA today were more proactive than the CSM were in the 1970s and 1980s in relation to enforcing the yellow card system and surveying the risks associated with medicine and medicinal products.

Named-Patient Basis

215. We invite the inquiry to make a finding that there was a lacuna in the regulatory framework, namely the ability to prescribe products on a named-patient basis, which resulted in patients being endangered. Further, we invite the inquiry to find that this lacuna exists today.

216. In certain circumstances, a medicinal product could be supplied for use by a patient in the absence of a Product Licence. One such circumstance was supply on a "named-patient" basis in accordance with section 9 Medicines Act 1968, whereby an unlicensed medicinal product could be specially prepared or specially imported to the order of a doctor or dentist for administration to a particular patient under their care.

217. Dr Rejman gave evidence that Professor Ludlam warned against using unlicenced product and that the MCA were concerned about unlicenced products. The letter from Professor Bloom and Dr Rizza in January 1982 to HCDs [**HCDO0000252_042**] demonstrates that the use of a product on a 'named-patient' basis was abused and used to circumvent regulatory controls.

218. The Medicines (Exemption for Licences) (Importation) Order 1978 came into operation on 3 November 1978. The Order required those importing medical products for use on a named patient basis to inform the Licensing Authority within 21 days of the first receipt of the product, and to keep records about the imported products.

219. The 1978 order was replaced from June 1984, by the Medicines (Exemption from Licences) (Importation) (Order) 1984. The order amended the requirement that the importer should inform the Licensing Authority within 21 days to provide that the importer should give the Licensing Authority prior notice in writing of the intention to import such a product and the quantity. The importer was also required to provide an undertaking that the quantity of the medicinal product did not exceed 25 single administrations or a course of treatment not exceeding 4 months and that they would inform the Licensing Authority of any matter coming to their attention which might reasonably cause the Licensing Authority to believe that the product could no longer be regarded either as a product which was of satisfactory quality for such administration. The Licensing Authority had the power to issue a notice preventing importation.

220. Dr Trevor William Barrowcliffe in his written evidence said that NIBSC did not have a role in monitoring importations on a named-patient basis. He thought it was a matter for the MCA.

221. It is apparent from the documents available that Konyne HT was still being imported and supplied in the UK on a named-patient basis in June 1990.

222. Today, regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicinal product which is supplied on a named-patient basis. This exemption flows from Article 5(1) of Directive 2001/83/EC.

223. Dame June Raine, in her evidence confirmed that the MHRA have no role or oversight of clinicians prescribing unlicensed products on a named-patient basis. They have provided guidance only. They advise that:

a. An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need;

b. Clinicians should inform patients that the product is not licensed.

224. However, the MHRA does not audit or take stock of the practice of prescribing on a named-patient basis. This is therefore entirely dependent on clinicians. This represents a large lacuna in the regulatory regime whereby clinicians can bypass licensing regimes and prescribe products to individual patients. Clinical freedom still has primacy over patient safety.

Blood Transfusion Practice & Policy

225. A proportion of those infected with contaminated blood during the relevant period were not haemophiliacs receiving factor concentrates but patients infected after receiving a blood transfusion. Those who received a transfusion in the absence of a clinical need for such a transfusion were infected unnecessarily. The blood transfusion they received neither saved their life nor improved their health outcomes following surgery. Far worse than that, those transfused unnecessarily received something inherently risky, which went onto have devastating consequences for them and their loved ones.

226. This section will comment upon the apparent lack of haemovigilance during the relevant period, whether we are any further forward today, and what should be happening to ensure the safety of the patients.

227. The recommendations we ask the inquiry to make to ensure the safe transfusion of blood in the future are detailed at the very end of our submissions.

228. In addition to the overarching finding we ask the inquiry to make – that there was a lack of haemovigilance during this period – we also invite the Inquiry to make the following findings:

a. In the 1960s, blood transfusion was seen as a "no harm done" type of treatment;

b. Clinicians failed to conduct an appropriate risk-benefit analysis in many cases;

c. Into the 1970s & 80s, those clinicians who did understand that blood transfusions are risky, still underestimated the risks posed by blood borne viruses, and focussed more on the risk of allergic reaction, ABO incompatibility, and bacterial infection;

d. Clinicians too readily transfused blood, which also impacted on the UK's push for self-sufficiency;

e. The practice of "single-unit top-ups" was a common (or not uncommon) practice amongst obstetricians; to give post-partum women one unit of blood to "pep them up" following delivery;

f. Blood transfusions were administered to post-partem women who had not experienced a haemorrhage which was life-threatening, instead, one unit of blood was thought to improve the health outcomes for mother and baby;

g. It was a common practice amongst surgeons and/or anaesthetists to transfuse 2 units of blood if they were going to transfuse 1, as it was thought 1 unit would make insufficient difference;

h. It was a common practice to transfuse patients back up to "normal" haemoglobin levels, rather than to transfuse patients back up to the amount required for them to be clinically stable, and then allow the patient to replenish their own levels in the days and weeks following surgery;

i. There was a general lackadaisical approach to blood transfusion, which would not have been the case had clinicians been educated properly in the inherent risk of viral disease present in blood;
j. Clinicians did not properly inform patients of the risks of transfusion, and took insufficient steps to "consent" patients;
k. The approach to what patients were told was paternalistic. Clinicians imparted the minimum information, withheld bad news, and used euphemisms to obscure their meaning. These behaviours combined to impede patient understanding, which disempowered patients;
l. Clinicians saw empowered, informed, and knowledgeable patients as a threat to their expertise; and
m. Blood transfusions did not always take place in a manner directly proportionate to the clinical need of the patient.

What Has Changed?

229. The Joint UKBTS Professional Advisory Committee (JPAC) was originally created in 1987 and has been subject to comprehensive review since 1998. JPAC prepare detailed service guidelines for UK Blood Transfusion Services.

230. By the 1990s, many (although not all) hospitals had Hospital Transfusion Committees (HTCs). HTCs were populated by volunteers. Clinicians aimed to improve the blood transfusion practices within the hospital, including avoiding unnecessary blood transfusion.

231. Since 1996, SHOT (Serious Hazards of Transfusion) have been collecting and analysing anonymised information on adverse events and reactions to blood transfusion. Where risks are identified, SHOT produces recommendations to improve patient safety. SHOT can also monitor the effect of the implementation of its recommendations.

232. From 2000 onwards, the NBS had a National Director for Hospital Transfusion Practice, formalising the arrangements for the improvement of blood transfusion practice.

233. SaBTO (Safety of Blood, Tissues and Organs) was set up as an advisory non-departmental public body, but with effect from 1st December 2012 it became a Departmental Expert Committee.

234. In the early 2000s, Professor Michael Murphy identified the following areas for improvement;

a. Multidisciplinary staff training in the process of blood transfusion;
b. The availability of Hospital Transfusion Practitioners;
c. Local approved protocols based on national guidelines for the appropriate use of blood;
d. Audit of blood transfusion practice;
e. The use of autologous blood transfusion; and
f. The provision of written information to patients on blood transfusion.

235. The work undertaken by SHOT led to a reduction in ABO incompatible red cell transfusions from 1996 to 2019. The number of red blood cell transfusions reduced by 30%. The mortality and morbidity rate also reduced.

236. Several surveys and audits took place which enabled SHOT and others to have a "bird's eye view" of blood transfusion practice, and patterns that emerged.

237. However, there remains room for improvement;

a. The implementation of electronic transfusion systems in the UK have been patchy and they are rarely used to their full functionality;
b. There remains a tendency amongst clinicians to transfuse patients due to low haemoglobin levels, or low red blood cell count levels, rather than due to a clinical need. Some clinicians are still transfusing patients to get

their blood count values back to normal when there is no haemorrhage. The focus should be on what patients require to be clinically stable;

c. Not enough use is made of alternatives to transfusion such as tranexamic acid;
d. The mechanisms required to support haemovigilance are not adequately resourced;
e. Haemovigilance comes at the bottom of the pecking order in many NHS Trust and Local Health Boards;
f. Due to budgetary pressures, many laboratory staff and transfusion practitioners have been cut;
g. Transfusion-transmitted infection (TTI), is often not recognised, and not attributed to transfusion;
h. Transfusion events do not always appear in a patient's primary health record;
i. Clinicians writing discharge letters to GPs on day (e.g.) 10 of a patient's time in hospital may not know that a transfusion took place on day 1 of the patient's admission;
j. Documentation of transfusion remains poor and inconsistent;
k. Patients are not always made aware they have received a transfusion, particularly where they received a transfusion while under general anaesthesia;
l. Patients are not always informed that there are risks attributed to blood transfusion;
m. Patients are not always advised to be vigilant for reactions or symptoms following a transfusion, and are not told what to do if they experience symptoms;
n. Patients are not always advised that infections arising from transfusion can lay dormant for many years;
o. There is a lack of integration between healthcare systems, leading to fragmentation, and ultimately patient information falling through the cracks;

p. The reporting systems for TTIs are not sufficiently sophisticated and robust for relevant parts of the haemovigilance system to identify an unknown viral agent as potentially transmissible by blood;
q. Clinicians do not have time to devote to haemovigilance initiatives such as SHOT, SaBTO, their HTC etc. This is due to pressures from universities and hospitals; and
r. There are still myths about blood transfusion practice which remain difficult to displace, despite the evidence basis.

What Needs to Happen

238. We say that the following tenets of best practice should be standard practice:
a. There should be greater use of electronic systems so that transfusions appear on the patient record;
b. Systems should be integrated;
c. There should be a standalone system which extracts information from all hospital systems and collates them into a central database;
d. There should be a more robust system in place for the reporting of adverse reactions to transfusion which occur because of viral infection, particularly where the virus lays dormant for many years;
e. Patients need to be informed that they have received a transfusion, that there may be consequences, and what to do if such consequences arise;
f. Patient information can be integrated into the standalone system – a tick-box exercise for clinicians where they select items from a drop-down menu which then generates a letter for patients with all the information relevant to their case;
g. GP surgeries and hospitals should share the same electronic system so that GPs know when patients have received a blood transfusion;
h. Something (e.g., wristband, a sticker in the notes, flag on the electronic system etc.) should follow the patient through their journey in hospital which records that a transfusion has taken place so that the clinician

writing the discharge summary knows that a transfusion has taken place;

i. Clinicians (or any other health care practitioner administering a blood transfusion) must record on the patient's notes that: (i) they consent to the transfusion; (ii) that the transfusion is compatible with the patient; and (iii) the justification for the transfusion;
j. HTCs should complete annual audits to determine which blood products are being used, in what quantity, and by which departments;
k. HTCs should record the number of transfusion reactions, transfusion incompatibility incidents, bacterial infections, viral infections, and any other adverse reactions as a result of the provision of blood or blood products (however long after the transfusion they present);
l. Patients should be encouraged to report any adverse health effects following a transfusion;
m. HTCs should report to SHOT and/or SaBTO on an annual basis;
n. Patients should only be transfused where the benefits outweigh the risks;
o. Patients should not receive transfusions to return their "numbers" to normal when there is no clinical need for a transfusion such as a haemorrhage;
p. The mechanisms to support haemovigilance should be properly resourced; and
q. Organisations who have clinicians within them who participate in haemovigilance initiatives such as SHOT, SaBTO, their HTC etc. should be remunerated, and those clinicians should receive a non-monetary benefit.

Candour, Cover-Up, and Openness

239. This section will cover:
    a. The candour of clinicians;
    b. The candour of civil servants;

c. The candour of government;

d. Organisational cover-up; and

e. What needs to happen in future to protect patients.

Candour of Clinicians

240. Doctors have a professional duty to be open and honest with patients about their care. Doctors are strictly regulated under the Medical Act 1983 and by the General Medical Council (GMC).

241. The GMC's Good Medical Practice (2013), states:

> *"(55) You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:*
> *a) put matters right (if that is possible)*
> *b) offer an apology*
> *c) explain fully and promptly what has happened and the likely short-term and long-term effects."*

242. No such guidance was contained within the "Professional Guidance" issued by the GMC in the 1970s. Nevertheless, we say that the above is common sense and should have been part and parcel of the duty to protect patients.

243. Our clients were not treated in this way; they were not provided with the common decency of being told the truth. We intend to examine some examples of this. It should be said that each and every one of our clients' stories are worth inclusion within this document. However, we know that the inquiry has a comprehensive note of our clients' oral evidence and has copies of their witness statements. We have therefore limited our examples to those which illustrate the wider points we wish to make.

Northern Ireland

244. One of our CPs had an appendectomy operation in 1985 at Tyrone County Hospital in Omagh. He received Factor VIII. No health care professional ever spoke to him or his parents about the potential risks involved in the use of Factor VIII. In 1992, he heard that a haemophilia patient had been treated with infected blood. His mother rang the hospital and spoke with a Junior House Officer to be told that they could not provide her son's blood test results relying on grounds of confidentiality, but "there was nothing to worry about' and "Everything would be okay".

245. He then spoke to Professor Mayne. She began the conversation by confirming that he did not have HIV but went onto say that he had contracted HCV from contaminated blood products administered after his appendectomy operation. He was told that if he looked after himself, this should not affect his life. He was not warned about sexual transmission, or the fact that HCV may develop into advanced liver disease.

246. Sadly, everything was not all right, as Professor Mayne had told him it would be. She must have known, given the committees she had sat on where NANBH/HCV was discussed, that all would not be all right. Still, she gave her patient false hope, which turned out to be a particularly cruel act of self-preservation. Our client developed liver abnormalities and required a course of treatment. He also suffered with depression. Matters were far from all right.

247. Even in the early 2010s, a doctor used the phrase 'people like you' during the consultation, the implication being that people who contract hepatitis are somehow less deserving of treatment, or that their lifestyle must be responsible for their infection.

248. Professor Mayne said the same thing to many of our clients in Northern Ireland. "Not to worry" is a consistent refrain throughout their evidence. They were given little to no information about risks of HCV or how it was

transmitted, even when supplied with leaflets. There is evidence of this lack of information being provided in **WITN0198004**, a letter from Professor Mayne dated 7 April 1999. It is dishonest by omission.

249. Paul Kirkpatrick's evidence is that Dr Mayne casually slipped into the conversation that he had contracted NANB Hepatitis in a routine clinic appointment in 1987. Later, she told him "Not to worry" and that he had probably had it for years and if he had not been affected yet then he would probably be okay. Again, everything was not okay.

250. He required treatment in the form of Interferon and Ribavirin in or around 1999. He tried to conceive, and it was only due to his wife's research that he discovered that they should have been trying to conceive while undergoing treatment. Dr Orla McNulty had told them there were no issues whatsoever and told them to continue their plans for the baby.

Wales

251. One anonymous witness gave evidence about his father who passed away in 1972. He thought his father to have been ill with leukaemia. A nurse told him and his mother to request a post-mortem, because he had died from asbestosis and might be able to claim compensation from Cardiff docks. He suspects this was her way of trying to reveal the truth in a system shrouded in secrecy. That nurse later left the profession entirely.

252. Our client and his mother were told that the Heath Hospital were not able to conduct a post-mortem because his father had hepatitis. Upon his death was the first time they were aware that his father had contracted the virus. They were given no information about the disease, including what kind of hepatitis it was.

253. It was only on reflection that our client looked back and saw things did not add up. At one point, after the blood transfusion, he and his mother were told to put on gowns and gloves to visit him. They were not informed of the reason for this, but in hindsight our client suspects it was due to the risk of infection.

254. It was not until they received a letter from the NBTS in 1973, 4 months after his father's death that they realised blood transfusion following an operation was the reason for the hepatitis infection. They responded to the letter, asking for more information, but never received a response.

255. Given their attempt to secure a Post-mortem had been unsuccessful, they were asked to conspire in the lies about the death of our client's father and accept leukaemia as the case of death.

256. Nothing about this situation was right. The actions of those who were supposed to provide health care in the aftermath of the death of our client's father was a performance, shrouded in deception, with the service that was supposed to care for him using smoke and mirrors to hide the truth. The dignity, respect, and honesty our client and his mother deserved was not afforded to them.

257. Next, we ask you to consider Janet Smith, whose son, Colin, had Haemophilia A. He was first injected with Factor VIII when he was 12 months old. This is confirmed by a letter from Professor Bloom dated 28 July 1983.

258. Janet described how she trusted Professor Bloom totally. He called his patients "his boys". She took this as a sign of how he cared for his patients. He did not tell her anything about the risks associated with Factor VIII.

259. Colin was 2 years old when Professor Bloom informed Janet that her son had HIV. She was told in a corridor in front of other patients. When Colin died, she

was informed that he had also been infected with HCV. They had not been told of this co-infection before his death. He was a PUP.

260. As a result of Colin's infection Janet and her family experienced the worst abuse imaginable. They were known locally as the AIDS family. Crosses were drawn on the door. "AIDS DEAD" was painted on the side of the wall. This suffering was in part caused by Professor Bloom's lack of candour in failing to advise Janet of the risks associated with Factor VIII.

261. Colin passed away on 13 January 1989 at the age of 7. He died at home. His death certificate records pneumonia, and AIDS due to contaminated Factor VIII, and haemophilia.

262. This tragedy ripped the family apart. Professor Bloom's lack of openness and honesty had devastating consequences. Colin's brother Daniel struggled to get married because he had lost his best man.

263. Susan Sparks gave evidence. She told the inquiry that when, on 15 September 1985, her husband, Les, who had Haemophilia B, was told he had HIV, Professor Bloom took them into a room and said, "don't worry about it but you have the antibodies for HIV, but it might not lead to AIDS." Here, were see that awful expression again; "Don't worry about it".

264. Susan feels guilty; she feels that she persuaded Les to have Factor IX treatment, and she will never forgive herself. Of course, she is not to blame. Les was under the care of Professor Bloom. He failed to inform either Susan or Les of the risks of Factor IX.

265. Les died on 24 March 1990. He was also infected with NANB Hepatitis, but there is no mention of this on death certificate

Findings We Want the Inquiry to Make

266. Over and over again, the inquiry has heard evidence from core participants and those infected and affected that clinicians failed to warn their patients of the risks of factor concentrates. The inquiry has a knowledge of risk presentation, and we do not intend to repeat the contents here but rely upon it as evidence that they knew about the risks.

267. There is no feasible explanation for the consistency of these accounts other than they are telling the truth.

268. Conversely, the clinicians who gave evidence to this inquiry were not telling the truth when they said they warned patients. Their credibility is seriously undermined. A particular example of this is the uniform amnesia that appears to have afflicted all those who attended the Excelsior Hotel at Heathrow on 24 January 1983.

269. It is inconceivable that they could they not remember what they were told at that meeting. The inquiry may remember Dr Peter Foster's reaction to the emerging AIDS threat in June 1983;

> "*My own feeling is that with an incubation period of one to three years and the first haemophilia case only 12 months ago, we may only be seeing the first puffs of smoke from the volcano.*"

270. We ask the inquiry to make the following findings:

a. Clinicians failed to warn patients of the risks before they were treated with factor concentrates;
b. Clinicians failed to be open and honest with patients about the infections they had and how they had obtained those infections;
c. Patients were lied to about the severity of the infections they had;
d. Clinicians failed to provide appropriate advice following infection;
e. Clinicians continued to distort the truth when giving evidence to this inquiry to suit their own narratives; and

f. There are fundamental issues concerning honesty which are endemic within the NHS, which has an attitude of covering up wrongdoing rather than admitting to it; and
g. There is also a culture of blame which leads to mistakes being hidden and lessons never being learned.

Dishonesty in Government

271. Mary Grindley gave compelling evidence about her husband, John, who was infected with HIV, and died on 14 June 1994, leaving his son, Tim, without the father he loved dearly. Again, he was never told of risks of Factor VIII.

272. Edwina Currie, a minister in DHSS, infamously said that "good Christian people" don't get AIDS. We say that this was the height of dishonesty. It was not only highly offensive, but untrue.

273. Understandably, Mary found this objectionable. She wrote to Mrs Currie and received the following response (written on Mrs Currie's behalf):

> "I *understand you take particular exception to Mrs Currie's reminder about good Christian people not catching the disease. She had in mind merely that for most people, a responsible and caring way of life should protect them and their loved ones from the threat of AIDS in future.*"

274. As well as demonstrating a total lack of empathy, this response demonstrates a mean-spirited attempt to blame those infected with HIV/AIDS for the disease. The Inquiry will be well-aware of the stigma and harassment experienced by those infected and their families. This certainly did not help the situation. More than that, it is an attempt to pull the wool over the eyes of those who had a right to know how they were infected.

275. John was diagnosed with HIV well before he was told about it, which further evidences the endemic lack of candour exhibited by clinicians at the time. The

deep tragedy of losing John was only exacerbated for Mary by the dishonesty, cover-up, and lack of candour by those in government. Mary told the inquiry that John said she could grieve for him for a year, and then find happiness with someone else. Mary was never able to move on. How could she, when the reason John had been infected was still being concealed from the world. She was never able to get over John's death. She said "*we have no closure, no admission of wrongdoing. Everything has been swept under the carpet and no one listened.*"

276. In **WITN2336007**, Mary provides letters and some responses she received from Government ministers and officials.

277. She experienced more intransigence when trying to obtain John's medical records. She was told his records had been destroyed when in fact she was able to obtain his records through the national haemophilia database. When she went to collect them, Doctor Savidge made it as difficult and undignified as possible for Mary, still grieving the loss of John.

278. Many of the responses received by Mary during her campaign contain the familiar "lines to take" which the Inquiry will have seen again and again in the documentation.

279. In a letter from DHSS dated 16 December 1983 to John Maples MP (who wrote to DHSS on Mary's behalf) it is said:

> "*The cause of AIDS is as yet unknown and there is no conclusive proof that the disease has been transmitted by American blood products. Nevertheless, I would like to assure your constituent that the Government is committed to making this country self-sufficient in blood products.*"

280. This response was dishonest. To say there is no conclusive proof without disclosing that there is strong evidence to suggest that the cause of AIDS was a

bloodborne virus was dishonest. It is deception by omission; a carefully chosen arrangement of words designed to hide the truth, not shine a light on it.

281. Further, in a letter received by Mary dated 18 April 1995 it is said:

> "[…] *government does not accept liability for those infected by contaminated blood products on the ground that such patients received the best treatment available, given the medical knowledge at the time.*"

282. These lines had become so entrenched due to intellectual dishonesty at the heart of government. We say that the dubiousness of this line should have been obvious to anyone parroting it.

283. Further, in November 2012, Mary received a response to a letter she wrote to then-Prime Minister David Cameron. The response was drafted on his behalf and said:

> "[…] *it has been the view of successive governments that there is no justification for a public inquiry, the relevant facts are already in the public domain.*"

284. Again, this is a line familiar to those who have seen the inter-departmental notes, briefings and "lines to take". This line that the relevant facts are already in the public domain fails to consider what those relevant facts might be, and how it is possible to determine what the relevant facts are without an inquiry into them.

285. It has taken far too long for this Inquiry to be held. Mary feels that she has failed John in death because still has not been able to get justice for him.

Dishonesty in the Civil Service

286. Dr Andrzej Rejman was senior medical officer (SMO) from March 1989 to July 1997, during the period where the HIV litigation was ongoing. Anita James's evidence was that Dr Rejman was a "law unto himself".

287. This can be seen at paragraph 5 of WITN5426006 where Dr Rejman said that there would be a large amount of material in the disclosure that discusses NANB which they may not want in the public domain. This demonstrates a lack of openness and honesty which should have been shocking. However, no one seems to have acted against Dr Rejman or passed their concerns up the line.

288. Anita James, knowing of Dr Rejman's options about the merits of the litigation, did not consider that this would affect his suitability to carry out the disclosure exercise. Nor did it seem to be a concern that he was not a lawyer. Ms James did concede that this was a task better done by a lawyer. Her response, on being given glimpses of Dr Rejman's lack of candour, appears to have been to keep her head down and not raise any concerns. There appears to have been a distinct lack of challenge and questioning surrounding the HIV litigation in particular.

289. The conduct of Dr Rejman during the HIV litigation is one example to illustrate the lack of candour. We rely upon the evidence of Andy Burnham and Jeremy Hunt and ask the Inquiry to make the following findings about lack of candour in the Civil Service:

    a. "Deadlock" is created by lines which are not justified or justifiable;
    b. Embedded deep within the Civil Service psyche is the fear of financial exposure at the exclusion of openness, candour, transparency, and accountability; and
    c. The Departmental Lines held (some of which have been reiterated during the course of this document), were at best inaccurate and at worse false;
    d. The DoH was more concerned about reputational damage than openness and honesty;

e. There is an institutional reluctance to listen to views of harmed patients;
f. "Group think" is a particular problem, whereby lines become entrenched because it is a facet of the civil service psyche to remain consistently in denial, even when contrary evidence is apparent and available;
g. There is a blame culture within the civil service and the NHS;
h. Civil servants provide briefings to ministers where some lines are delivered without any caveat or caution that the opinions expressed are contentious.

Where are we Now?

Wales

290. Eluned Morgan MS (Minister for Health and Social Services) has launched a consultation concerning the statutory duty of candour in September 2022. The consultation period is ongoing.

Northern Ireland

291. In January 2018, Justice John O'Hara published his report on the Inquiry into Hyponatraemia-Related Deaths. His first recommendation was that a statutory Duty of Candour should be enacted in Northern Ireland and that it should apply to Healthcare Organisations and everyone working for them. Justice O'Hara also recommended that criminal liability should attach to breach of this duty and to obstruction of another in the performance of this duty.

292. The consultation closed on 31 August 2021, and the responses received are currently being analysed for consideration by the Duty of Candour Workstream and its Being Open Subgroup.

What Needs to Change

293. We have provided our detailed recommendations at the end of this document. However, we would like to make the following broader points:

a. Clinicians should be transparent with patients from prescribing a medicine through to informing the patient of any errors, mistakes, or wrongdoing;
b. Where clinicians make mistakes, there should be an open and honest environment which supports learning;
c. However, where clinicians try to cover up mistakes, this should be dealt with severely, as it is so much worse to cover up a mistake than to make a mistake in the first place;
d. Government departments should be vibrant places where fresh ideas are generated and old, stale lines are challenged;
e. There should be a culture of challenge, looking at an issue from all angles, and intellectual probity within Government;
f. Ministers and civil servants should communicate honestly with the public about public health risks and issues; and
g. Where something has gone wrong, the immediate instinct should be to investigate what has gone wrong, including sanctioning a judge-led inquiry where appropriate, rather than covering up what has gone wrong in the hope those affected will simply give up hope.

Hepatitis B

294. Since the inception of the disparate trusts and schemes, those infected with HBV have been omitted from the schemes. The Government justification is that those infected with HBV do not fall into the same "*special circumstances*" as those who were infected with HIV and HCV, because screening was introduced in 1972.

295. There is no proper justification for treating those infected with HBV differently from those infected with HIV and HCV, because the first-generation screening

for HBV in 1972 was not particularly efficacious and, even after the vaccine was introduced in 1982, infections continued to happen. Rather, the point is that in respect of both HBV and HCV, mitigation was taken which was insufficient to prevent transmission and patients were infected by imported concentrates, which the DHSS knew were dangerous.

296. Dr Tony Napier stated that the tests for HBV introduced in the early 1970s were not particularly sensitive but as the decade went on more sensitive tests were introduced. Dr Morris McClelland agreed that HBV screening did not eliminate completely HBV.

297. Certainly in June 1975, imported concentrates continued to transmit HBV [**TREL0000074_028**].

298. A UKHCDO hepatitis working party report for 1984/5 confirmed 22 cases of HBV in 1984 [**CBLA0002279_001**]. It stated that there had been no decline in the incidence of HBV despite the availability of the HBV vaccine.

299. As late as August 1989, Cutter Koate HS was implicated in HBV infection in the UK and in Japan [**BAYP0000016_011**].

300. The se submissions also rely upon the Penrose Report, Chapter 25 §§ 25.51, 25.53, 25.62, 25.85, 25.87, 25.97 and 25.101 to establish that HBV screening was not efficacious after its introduction in 1972 and for some time thereafter.

301. The Rt Hon Matt Hancock MP (then Secretary of State for Health) and Mr Vineall (a senior civil servant) gave to the Infected Blood Inquiry in May 2021. The relevant evidence is at pp 144 – 147 of the transcript. Mr Vineall confirmed that he had seen no documents that expressly considered the inclusion of persons infected with Hepatitis B in EIBSS.

302. The Court of Appeal in *R (CN) v Secretary of State for Health* [2022] EWCA Civ 86, [2022] 4 WLR 73 rejected a discrimination claim pursuant to article 14 ECHR on the basis of the discretion available to the Secretary of State for the formulation of policy. However, this Inquiry is a more intense review of the decisions, or lack of decisions, made in relation to HBV and the support provided to those infected with viruses through their treatment with imported concentrates.

RECOMMENDATIONS

Healthcare

1. **The UK and Devolved Governments must establish multi-disciplinary centres of excellence for the treatment of persons infected by blood and blood products.** Such centres should provide access to all medical advice (including consultant hepatology, consultant genitourinary and consultant neurology), treatment, dentistry and specialist social work support that is commonly required by those who have been infected with HIV or Hepatitis, with routine consideration being given to whether any referral should be prioritised. Further, the Department of Work and Pensions should undertake assessments for the purpose of applications for Personal Independence Payments at such centres and provide bespoke training to the assessors who will be carrying out such assessments, drawing upon advice from the practitioners who operate from the specialist centres.

2. **The UK and Devolved Governments should make available specialist mental health services to persons infected by blood and blood products and those affected by such infections, at a Trust or Health Board independent of the Trust or Health Board who treated the infected person when they became infected.**

3. They must also establish a UK wide system of counselling for those infected and affected by blood and blood products. The system should be accessible throughout the UK whenever and wherever the person may require it.

4. The UK and Devolved Governments should design and implement a scheme which will confirm that a person has been infected by blood or blood products. This will be done in two ways:

   a. **A Health Card will be issued to every person infected by blood or blood products.** Its appearance will be similar to that of a credit card. The production of this card will alert a health care employee that the holder of the card has been infected with infected blood. To maintain confidentiality there will be nothing on it to indicate the purpose of the card. This card will be sufficient for a person to require priority to treatment.
   b. **The UK and Devolved Governments should design and implement a Health Passport for persons infected by blood and blood products** – so that upon presentation a health care employee can see: (i) a statement of that fact that the person was infected by blood or blood products; (ii) the current status of the persons infection (presently infected, cleared, suppressed etc); (iii) the person's illnesses, symptoms and treatment side-effects; (iv) the person's treatment regime; (v) medicines that should not be prescribed; (vi) if applicable, the severity of the person's haemophilia (or Von Willebrand's Disease) and its complications; and (vii) the necessary destination for ambulatory services (paramedics should be provided with information and training in relation to the health passport). The Health Passport would require regular updating by the treating clinicians and should appear in a prominent way when the person's records are accessed digitally and should be provided in hard copy to the infected person. The digital passport should work across all the UK Health Departments (so that a person usually resident in one part of the UK is not disadvantaged if they need to access

healthcare provision in another part of the UK) and should appear to emergency call operatives.

5. **The UK Health Departments should adapt the criteria for organ transplants so that: (i) persons infected by blood or blood products are able to receive a liver transplant after the age of 70; (ii) prioritisation criteria which disproportionately affect persons infected by blood and blood products should be identified and disapplied in their cases; and (iii) the fact that a person was infected by blood or blood products should be a criterion which is adopted so that it leads to greater prioritisation** (bearing in mind that liver failure develops more quickly in persons infected with Hepatitis C than other causes and they have been infected for decades).

6. **The Medical Research Council should establish and fund research into the association between Hepatitis C and brain disease, including but not limited to cognitive impairment, trans-ischaemic attacks, strokes, and dementia.** As an adjunct to this recommendation, clear guidance should be published by the Royal College of Pathologists on the decision to perform, and the conduct of, an autopsy of the brain for the purposes of such research (with the consent of the next of kin) where a deceased person was informed that they were at risk of vCJD infection, and the necessity to ascertain whether they in fact present a risk, to eradicate blanket refusals to carry out post-mortem examinations.

7. **The UK Health Departments should ensure that treatment for HIV is available at a place other than at a GUM clinic for those who were infected through blood and blood products.**

8. **The National Institute for Clinical Excellence should recommend that the children of haemophiliacs who were infected by blood and blood products should be permitted more than one round of IVF and egg selection to remove haemophilia carriers, to relieve anxiety relating to lifelong treatment for their children.**

9. **The UK Health Departments should ensure that persons infected with Hepatitis C through blood or blood products is offered an appointment with a hepatologist and routine fibro scans (every 6-12 months as appropriate).**

10. **The UK Health Departments should conduct a review of the umbrella approach to vCJD at-risk notifications** and consider whether persons infected by blood and blood products should continue to be considered at-risk for public health reasons, especially where it can be proven by taking all reasonable steps that they did not receive an implicated product or transfusion.

Blood Transfusion Practice

11. Where a clinician or health professional has administered or authorised a blood transfusion in contravention of the guidance contained within JPAC's Transfusion Handbook, this should be *prima facie* evidence for any GMC/NMC referral.

12. The implementation of SHOT and SaBTO's recommendations by NHS Trusts and Local Health Boards should be monitored by the Department of Health, with a failure to comply being prima facie evidence of the Trust or Health Board needing to go into special measures.

13. Trusts, Health Boards, Universities, and Hospitals should receive remuneration where they employ clinicians who partake in haemovigilance initiatives.

14. **The UK Health Departments should fund the implementation of a standalone electronic system** which provides for:
    a. The integration of GP and Hospital systems;
    b. The integration of systems between Health Boards and Trusts;

c. Allows for data to be collected by the UKHSA, SaBTO, JPAC, and SHOT; and

d. Allows a single reporting portal for:

   i. Serious Adverse Events;

   ii. Serious Adverse Reactions;

   iii. Near misses;

   iv. TTIs; and

   v. Any other relevant information concerning transfusions.

15. **Medical Schools should be required to cover haemovigilance as part of the curriculum**.

16. The GMC should be able to veto curricula developed by medical schools and provide recommendations for improvement.

17. Where any healthcare practitioner administering a blood transfusion fails to: (i) ensure the patient consents to the transfusion; (ii) record the patient's consent; (iii) record that the transfusion is compatible with the patient; and (iv) record the justification for the transfusion, this should be *prima facie* evidence for a GMC and/or NMC referral.

18. The UK Health Departments should ensure that Hospital Transfusion Committees: (i) complete annual audits to determine which blood products are being used, in what quantity, and by which departments; (ii) record the number of transfusion reactions, transfusion incompatibility incidents, bacterial infections, viral infections, and any other adverse reactions as a result of the provision of blood or blood products (however long after the transfusion they present); and (iii) report the same to SHOT.

19. **The UK Health Departments should adopt into guidance the recommendations contained within SHOT and SaBTO's annual reports.**

Education

20. **The Royal Colleges should work collaboratively to design and implement an education programme for all established practitioners to be undertaken as part of continuing professional development and for students of medicine or dentistry to raise awareness of Hepatitis C in relation to: (i) the symptoms of present infection; (ii) the consequences of past infection; (iii) infection through blood and blood products; and (iv) the long incubation period.**

21. **The Chief Medical Officers of the UK and Devolved Governments should send a letter to all doctors to raise awareness of Hepatitis C in relation to: (i) the symptoms of present infection; (ii) the consequences of past infection; (iii) infection through blood and blood products; and (iv) the long incubation period.**

22. **The UK and Devolved Governments should design and implement a public health campaign to raise awareness of Hepatitis C in relation to: (i) the symptoms of present infection; (ii) the consequences of past infection; (iii) infection through blood and blood products; and (iv) the long incubation period.**

23. **The UK and Devolved Government should make available routine screening via general practitioners and pharmacies for those who reasonably believe they may have been infected with Hepatitis C through blood and blood products, followed by a mandatory referral into the centres of excellence following a positive rest result.**

24. **The Royal Colleges should recommend a question relating to the receipt of blood and blood products prior to 1991 on routine health screening by general practitioners.**

Social security

25. **The Secretary of State for Work and Pensions in conjunction with the Secretary of State for Health, the Welsh Ministers, the Scottish Ministers and the Northern Ireland Executive should consult upon, design and implement a decision making tool for disability assessments which involve those infected by blood and blood products and that tool should be made publicly available to infected persons and used by assessors** so that there is a common understanding of the symptoms of infections, the effects of treatment and the criteria applied by assessors. Any targets that are set by the Department of Work and Pensions for private contractors in the procurement of assessments should be disapplied to those infected by blood and blood products.

Duty of Candour

26. **The UK Government should introduce legislation to Parliament to strengthen the duty of candour imposed on NHS bodies[8] and all healthcare practitioners who provide care and treatment to a patient to inform them of significant risks of treatment and positive test results as soon as is reasonably practicable and creating new statutory offences for breach of the duty –** the duty should apply where a health professional becomes aware or has reason to suspect that a patient has not been informed of significant information about their health.

27. The UK Government should introduce legislation to Parliament to impose a duty on Government and its advisors not to make misleading statements (unjustified assurances) in press releases or Parliamentary statements in relation to the knowledge of emerging health risks, the severity of risk and the level of risk posed to the population.

[8] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulatio n 20

28. **The UK and Devolved Governments should design and implement a comprehensive lookback exercise to identify, as far as is possible, all patients who may have received blood or blood products derived from donations which subsequently tested positive or whose donor subsequently tested positive and compile a comprehensive database of interrogable data by reference to a patient's NHS number.**

29. **The UK Government should introduce legislation to Parliament, with the consent of the Devolved Legislatures, to: (i) make the destruction of patients' medical records an offence; (ii) to make it a legislative requirement that all notes are recorded on the patient's records; (iii) to allow access to medical records free of charge; (iv) to require each hospital to appoint a medical records manager whose duties involve ensuring the secure and effective storage, retention and retrieval of medical records.**

<u>Conflicts of Interest</u>

30. **The UK Government should introduce legislation to Parliament imposing a requirement on doctors to disclose any potential conflicts of interest (including any transfers of value made by pharmaceutical companies) to a publicly available register of potential conflicts of interest (such as the General Medical Council register).**

31. **The UK Government should introduce legislation to Parliament imposing a requirement on pharmaceutical companies to report payments made to teaching hospitals, research institutions and individual clinicians.**

32. **The UK Government should introduce legislation to Parliament requiring all bodies discharging or assisting in the discharge of the functions of the UK Health Departments to adopt a code of conduct requiring the declaration of potential conflicts of interests by all persons involved in the decision making processes of such bodies or who provide advice to those who are,**

and requiring such bodies to proactively consider whether any conflicts of interest exist by reference to the register of interests or otherwise.

33. **The UK and Devolved Governments should jointly establish a register of organisations and advisory committees which include doctors as members or advisors and publish in the register the names of the members, advisors, and observers** (which would include bodies such as the UK Haemophilia Centre Directors' Organisation and the Haemophilia Reference Centre Directors' Meetings).

34. **The General Medical Council should introduce a restriction on doctors receiving disproportionate hospitality from the pharmaceutical industry and publish guidance on what amounts to disproportionate hospitality.** Such guidance should, for example, make it clear that travel expenses and hotel accommodation for medical conferences must be paid for by the clinician or their employer and they must not be reimbursed by commercial enterprises or otherwise receive benefits in kind, save where the clinician is invited to give a presentation in which case, they are allowed to recover reasonable expenses from the organiser of the event or conference.

Financial Schemes

35. **Any new financial schemes which may be established in response to the Inquiry must be administered by the UK Government**, because: (i) they are not devolved matters; and (ii) to avoid unjustifiable differences in treatment of those infected and affected by the UK and Devolved Governments.

36. **Persons infected with Hepatitis B through blood and blood products should be included in any new financial schemes** as infections continued to occur after the introduction of routine screening in 1972, particularly as HBc testing was not introduced across the UK.

Regulation of medicines and medicinal products

37. **The UK and Devolved Governments should establish a body with the function of monitoring the use of unlicenced medicines and medicinal products,** to whom doctors must report when they prescribe unlicensed medicines and medicinal products and inform them of any adverse health reactions that may be associated with the unlicensed medicine or medicinal product. Such a body should monitor trends in the prescription of unlicenced medicines and medicinal products and look for unjustified prescribing and trends in adverse reactions.

38. **The General Medical Council should make it a requirement that where a doctor prescribes an unlicenced medicine or medicinal product, the patient is informed of the fact that the medicine or medicinal product is unlicenced, why its use is justified in that particular case, what all of the significant potential risks are, and that the conversation is recorded and signed by the patient.**

39. **The Medicines and Healthcare products Regulatory Agency ('MHRA') should review its enforcement of licence conditions to ensure it has effective systems in place to monitor that warnings relating to adverse health reactions are given to patients for a licenced product.**

40. **The UK Government should introduce legislation to Parliament mandating the reporting of adverse health reactions to licenced medicines and medicinal products to the MHRA and establishing a register of adverse reactions which can be interrogated by the MHRA and others to identify emerging trends.** The Patient Safety Commissioner should investigate any complaints of a failure by a doctor to report an adverse health event.

41. **The online portal for patients to use the yellow card system should be made more user friendly, more easily understood and used by the patient.**

Emerging health risks

42. **The UK Health Departments should establish systems for the monitoring, collecting, assimilation and distribution of worldwide published scientific papers to ensure that medical officers, health officials and (where appropriate) clinicians are made aware of developing knowledge of emerging risks.**

43. **The UK Health Departments should establish guidance for their medical officers and health officials on their roles and responsibilities in respect of the monitoring, collection, assimilation, and distribution of published scientific papers on emerging health risks to ensure that information about health risks is received by the appropriate person and all necessary decisions based on the evidence are taken as soon as is reasonably practicable.**

44. **Such guidance should also set out when epidemiological advice should be sought in response to information about an emerging health risk.** *On this point, we submit that the Inquiry should call evidence about the response of the UK and Devolved Governments to the current outbreak of hepatitis in children to assess how the current systems operate.*

45. **UK and Devolved Government medical officers should normally apply the precautionary principle to emerging health risks**. This means identifying and implementing all reasonable steps to mitigate the risk of infection in at-risk groups when an association, rather than a causal link, is established by the science. The more serious the consequences of infection, the more action is likely to be reasonable.

Redress

46. **The UK Government should accept all the findings made by the Inquiry and apologise for any failures or wrongdoing.**

47. **The General Medical Council should investigate any fitness to practice concerns arising from the evidence received by the Inquiry.**

48. **The Charity Commission should investigate any failures or wrongdoing by the trustees and/or employees of the Alliance House Trusts.**

49. **The UK Government should introduce legislation to Parliament, with the consent of the Devolved Legislatures, establishing a Commissioner for Persons Infected and Affected by Blood and Blood Products, assisted by an advisory panel of infected and affected persons** (as was done in Northern Ireland with the Commissioner for Survivors of Institutional Childhood Abuse (COSICA)**)**. The Commissioner should have the duty to encourage and monitor the provision and co-ordination of relevant services in the UK and provide information on how to access services and support, including services to improve physical or mental health and provide counselling. The Commissioner should be furnished with a number of statutory powers to:

    a. Undertake or commission research into matters concerning the interests of infected and affected persons;
    b. Compile information concerning the interests of infected and affected persons;
    c. Provide advice or information on matters concerning the interests of infected and affected persons;
    d. Publish anything concerning the interests of infected and affected persons;
    e. Make representations or recommendations to any person concerning the interests of infected and affected persons.

Lloyd Williams KC

Christian J Howells

Laura Shepherd
30 Park Place, Cardiff
16 December 2022